UNITED NATIONS

UNEP

SC

UNEP/POPS/POPRC.14/3

Distr.: General
9 May 2018

Original: English

Stockholm Convention on Persistent Organic Pollutants

Persistent Organic Pollutants Review Committee
Fourteenth meeting
Rome, 17–21 September 2018
Item 4 (b) of the provisional agenda*

Technical work: consideration of a recommendation to the Conference of the Parties on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds

Further assessment of information on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds

Note by the Secretariat

I. Introduction

1. By its decision POPRC-13/2, on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds (see UNEP/POPS/POPRC.13/7, annex I), the Persistent Organic Pollutants Review Committee at its thirteenth meeting decided to recommend to the Conference of the Parties that it consider listing PFOA, its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions as specified in paragraph 2 of that decision.

2. In paragraphs 3, 4 and 5 of the same decision, the Committee invited Parties and observers to provide the following information by 12 January 2018:

(a) Information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

(i) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socioeconomic aspects;

(ii) Transported isolated intermediates in order to enable reprocessing in another site than the production site: information on the quantities used, extent of transport and risks, and use;

(iii) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;

(iv) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;

* UNEP/POPS/POPRC.14/1

(v) Photo imaging sector: information on paper and printing, and information relevant for developing countries;

(vi) Automotive industry: information on spare parts;

(vii) Fire-fighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of fire-fighting foam mixtures;

(b) Information that would assist the further evaluation by the Committee of those chemicals in relation to their unintentional formation and release, in particular from primary aluminium production and from incomplete combustion;

(c) Information that would assist the further evaluation by the Committee of the chemical identity of PFOA-related compounds chemical list.

3. Pursuant to paragraph 9 of the same decision, the Secretariat has compiled the information provided in accordance with paragraphs 3, 4 and 5 of that decision, and made it available on the website of the Stockholm Convention.[1]

4. Furthermore, pursuant to paragraph 6 of the same decision, the Secretariat has prepared a document on note (ii) of part I of Annex A to the Convention and the scope of the reference to stockpiles within Article 6 of the Convention (see UNEP/POPS/POPRC.14/INF/6), for consideration by the Committee at its fourteenth meeting. The document was prepared following the collection of information from Parties through a questionnaire.

5. In paragraph 10 of the same decision, the Committee established an intersessional working group to assess the information provided in accordance with paragraphs 3, 4 and 5 of that decision with the intention of strengthening the recommendation on the listing of the chemicals for consideration at its fourteenth meeting.

6. The draft assessment of the information prepared by the intersessional working group is set out in the annex to the present note, without formal editing. A compilation of comments and responses relating to the draft assessment is set out in document UNEP/POPS/POPRC.14/INF/7.

II. Proposed action

7. The Committee may wish:

(a) To review the draft assessment of the information provided in accordance with paragraphs 3, 4 and 5 of decision POPRC-13/2 on PFOA, its salts and PFOA-related compounds set out in the annex to the present note, and consider including it in an addendum to the risk management evaluation on those chemicals that was adopted by the Committee at its thirteenth meeting[2];

(b) To consider strengthening its recommendation to the Conference of the Parties on listing PFOA, its salts and PFOA-related compounds, taking into account the information set out in the annex to the present note and in document UNEP/POPS/POPRC.14/INF/6.

[1] http://chm.pops.int/tabid/6174/Default.aspx.

[2] See UNEP/POPRC/POPRC.13/7/Add.2.

Annex

FURTHER ASSESSMENT OF INFORMATION ON PFOA, ITS SALTS AND PFOA-RELATED COMPOUNDS

Draft addendum to the risk management evaluation on PFOA, its salts and PFOA-related compounds[1]

May 2018

[1] UNEP/POPS/POPRC.13/7/Add.2.

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Executive Summary

1. In June 2015, the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds[2] in Annexes A, B, and/or C to the Stockholm Convention (UNEP/POPS/POPRC.11/5). At its twelfth meeting in September 2016, the Persistent Organic Pollutants Review Committee (POPRC) concluded that PFOA is persistent, bioaccumulative and toxic to animals including humans. There is widespread occurrence of PFOA and a number of PFOA-related compounds in environmental compartments and in biota and humans. Therefore, PFOA, its salts and PFOA-related compounds that degrade to PFOA are likely, as a result of their long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted (UNEP/POPS/POPRC.12/11/Add.2).

2. At its thirteenth meeting in October 2017, the POPRC adopted the risk management evaluation (RME) on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2) and recommended to the COP that it consider listing the chemicals in Annex A or B to the Convention with specific exemptions specified in decision POPRC-13/2 (also in UNEP/POPS/POPRC.13/7/Add.2, para 13). However, the Committee was unable to reach conclusions on whether exemptions may be needed for specific uses. Furthermore, additional work was needed to consider the possibility of unintentional releases and specific issues related to substance identity.

3. The Committee established an intersessional work group to assess additional information to help further the discussion at the fourteenth meeting to define the need for possible specific exemptions and/or acceptable purposes for certain additional applications and to evaluate their unintentional releases in the view of strengthening its recommendation to the COP. The Committee invited Parties and observers, including the relevant industries, to provide information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

(a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects;

(b) Transported isolated intermediates in order to enable reprocessing in another site than the production site: Information on the quantities used, extent of transport and risks, and use;

(c) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;

(d) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;

(e) Photo imaging sector: information on paper and printing, and information relevant for developing countries;

(f) Automotive industry: information on spare parts;

(g) Firefighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures.

4. For the applications above, information regarding socio-economic aspects as well as other relevant information was also requested.

5. In addition, the Committee invited Parties and observers to submit information that would assist the further evaluation by the Committee of PFOA, its salts and PFOA-related compounds in relation to its unintentional formation and release, in particular from primary aluminium production and from incomplete combustion.

6. The Committee also invited Parties and observers to provide information that would assist the Committee to further evaluate the chemical identity of the PFOA-related compounds chemical list; in particular in relation to sulfluramid and 1-hydroperfluorooctane (1-H-PFO). Sulfluramid is manufactured by using perfluorooctane sulfonyl fluoride (PFOSF) as an intermediate and its structure is related to perfluorooctane sulfonic acid (PFOS). In the environment, it degrades in significant yields to PFOS although it also has the potential to degrade to PFOA under certain conditions. Therefore, sulfluramid should be dealt with under the listing of PFOS, its salts and PFOSF according to Annex B to the Stockholm Convention rather than under the listing of PFOA. Based on the further information submitted, 1-H-PFO should not be excluded from the scope of PFOA-related compounds since studies

[2] PFOA-related compounds are differently defined according to the chemical scope in different approaches. In this document, the term "PFOA-related compounds" is used as defined in section 1.1. If quoted from other information sources the original wording of analogue terms, such as "PFOA-related substances" (e.g. used in ECHA 2015a), is maintained.

suggest that a transformation to PFOA is possible. 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate (CAS No: 93705-98-7) should be included in the non-exhaustive list of PFOA-related compounds.

Unintentional formation and release

7. The RME identified that PFOA, its salts and PFOA-related compounds could potentially be unintentionally formed from incomplete combustion and primary aluminium production but that further information was needed on this topic. Additional information on unintentional formation and release of PFOA, its salts and PFOA-related compounds was provided by Austria (2018), the Netherlands (2018a) and International POPs Elimination Network (IPEN) and Alaska Community Action on Toxics (ACAT) (2018). They provided substantiated information detailed in the RME for releases of PFOA from incomplete combustion sources. Additional information and preferably also measurements / quantitative data from other incinerators, open burning and other sources of unintentional formation would be desirable. It is also noted that in developing and transition countries there is greater prevalence of open burning and other uncontrolled combustion processes, and these should also be considered. The Netherlands (2018a) highlighted that an addition to Annex C would need to not only be justified but proportionate, highlighting that the emission is negligible (0.057 g/yr) compared to all the other sources. No new information on unintentional releases of PFOA linked to aluminium production were provided. Most of the information identified in literature and detailed in the RME relates to emissions of CF_4 and C_2F_6, which are unrelated to PFOA. From the currently available information it is not possible to conclude that aluminium production represents a relevant source of PFOA releases to the environment.

Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment

8. The RME for PFOA highlighted a potential need for more information about a possible exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. Specific information on membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment has been provided by Canada, China, Mexico and IPEN and ACAT. Furthermore, relevant information has been identified in the submissions from Health Care Without Harm Europe and MedTech Europe related to medical devices. Several potential alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME, including those that meet regulatory requirements and are in current use. In addition, no specific application has been identified that requires C_8 chemistry. Based on the evaluation of available information no exemption is needed for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment.

Transported isolated intermediates

9. The RME for PFOA highlighted a potential need for more information about a possible exemption for transported isolated intermediates. The Committee requested information related to the quantities used, extent of transport and possible risks, and use. Additional information was submitted by IPEN and ACAT and Archroma (a member of FluoroCouncil). Archroma reported about the risk management measures in place. Based on the evaluation of available information a time limited exemption could be considered for perfluorooctane iodide (PFOI) as an isolated intermediate to enable reprocessing at another site than the production site.

Medical devices

10. For medical devices, the European restriction (EU 2017/1000) allows an exemption for all medical devices (excluding implantable ones) of 15 years and a non-time limited exemption for implantable medical devices. However, on the other hand the RME (UNEP-POPS-POPRC.13-7-Add-2) highlights that alternatives to PFOA for manufacture of PTFE exist and have been commercialised. A report by ECHA (2015a) as part of the European restriction estimates total quantities in use for medical devices amounts to <5kg of PFOA globally. MedTech (2018) and Euromed (2015) both highlighted the difficulty in producing detailed lists of specific applications within healthcare due to the diverse ways in which polytetrafluoroethylene (PTFE)[3] is used, though alternatives for PFOA and PFOA-related compounds in medical devices have passed stringent regulatory requirements in some geographies and are already in use. However, MedTech, (2018) highlighted that due to the stringent regulations for substitution in the healthcare sector, if changes are made to articles this can trigger the need for a new round of clinical trials (taking years to complete). Based on the information compiled and discussed within the RME and further elaborated upon within the current addendum, examples exist cases where medical devices made without PFOA are available on the market and in use. However, the evidence reviewed suggests that phase-out is still ongoing for some uses and that a time-limited exemption may be needed for medical devices to prevent loss of critical applications. However further detail on specifically which applications are critical is needed for further resolution.

[3] PFOA can used as an emulsifier in the manufacture of PTFE, and would be present as a by-product of the finished product.

Implantable medical devices

11. The RME for PFOA highlighted a need for more iinformation about a potential exemption for medical implantable devices due to possible presence as a by-product in PTFE. Quantities of PFOA and PFOA-related compounds used in the production of PTFE found in impllantable medical devices are small. As an indicative estimate for order of magnitude a manufacturer commented that the EU total is 20g in all devices put on the market during the period 2018–2025. This would lead to and estimation of ll00g worldwide (ECHA, 2014a). ECHA (2015b) reported during the EU REACH restriction that during the manufacture of PTFE, concentrations of PFOA as a by-product range from 0.0001 to 0.5% wt/wt PTFE. A further personal communication with ECHA (2018) highlighted that during the discussions with industry working concentrations of PFOA specifically within implantable medical devices were likely to be much lower again. However, alternatives such as PFOA free PTFE products have undergone clinical testing, and been approved for use in some geographies. This includes the use of PFOA free PTFE products for guidewires in the USA (Nesbitt, 2017). Limited additional information has been provided on the extent of transport, risks and socio-economic impacts of a possible restriction however the low quantities presently being used in implantable medical devices would also mean low potential for exposure. Similarly, additional information on the use of PFOA in medical implants in developing countries is unknown. A time-limited exemption for this use should be considered.

Photo imaging sector

12. At POPRC-13, representatives of the European photographic industry provided information for the RME that suggested time-limited exemptions for photographic coatings applied to paper and for use in printing plates are no longer needed. Non-perfluorinated alternatives have successfully replaced most uses in the imaging and printing industry and the move to digital imaging will replace the need for PFOA. I&P Europe (2016) comment that use of PFOA compounds in photo imaging has decreased globally by 95% since 2000 and only limited critical applications (limited to photographic coatings applied to films only) still use PFOA. However, it was also noted that for developing countries, such information was lacking. New information provided by the Netherlands (2018a), IPEN and ACAT (2018) and Healthcare Without Harm (HCWH, 2018) indicates that analogue printing is being phased out and replaced rapidly by digital, including in developing and transition countries. Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transitional countries, and the further reduction in use of PFOA in this sector, no exemptions for photographic coatings applied to paper and printing plates should be considered necessary.

Automotive industry

13. The RME for PFOA highlighted a need for more information about a potential PFOA exemption for automotive service and replacement parts. Specification of relevant automotive service and replacement parts as well as sound justification for any exemption is required. Relevant information was submitted by the Canadian Vehicle Manufacturers' Association (CVMA, 2018), European Automobile Manufacturers Association (ACEA, 2018), Society of Indian Automobile Manufacturers (SIAM, 2018) and IPEN and ACAT (2018). Furthermore Canada (2018) indicated that the drafters should look at paragraphs 79, 89 and 232 of the RME as being relevant to the current document. Based on the evaluation of updated information a time limited exemption could be considered for automotive service and replacement parts and vehicles. So far, no conclusive information has been provided on specific relevant service a id replacement parts and on the quantities of relevant substances used in different applications. Information such as amounts of PFOA and related compounds used in different parts is considered supportive to justify a consideration of a recommendation for an exemption. Further additional information such as time required for phase-out, estimation of economic impacts, and potential alternatives already in place, and retrofitting capacity would support further discussions at international level.

Firefighting foams

14. Fire-fighting foams were identified as a dispersive use of PFOA in the RME resulting in direct release to the environment. Perfluorinated compounds within fire-fighting foams have been used because they proved effective against liquid fuel fires (Class B) (ECHA, 2014a). In the past C_8 based perfluoro technologies were mostly used, including PFOS (now recognised as a POP under the Stockholm Convention) and PFOA. Seow (2013) comments that the primary intentional use of PFOA within fire-fighting foams was as the ammonium salt (APFO). Where concerns over the human health and environmental effects of C_8 technologies were raised, industry largely moved towards shorter-chain C_6 perfluorinated compounds manufactured through telomerisation. The Swedish Chemicals Agency (2015) highlights that while C_6 fluorotelomers are not manufactured using PFOA, the reaction process can create C_8 species including PFOA as a by-product. Seow (2013) also comments that some other perfluorinated compounds (greater than C_6) within C_6 fluorotelomer products can degrade into PFOA in the natural environment, such an example includes acrylamide-based fluorosurfactant (CAS No: 70969-47-0).

15. Information on in-use stockpiles and mixtures was provided by Belarus (2018), Netherlands (2018a), Sweden (2018), the Fire-Fighting Foams Industry Coalition (FFFC, 2018), and IPEN and ACAT (2018) as a joint submission. Only limited information on the existing stockpiles of PFOA based fire-fighting foams was available.

16. A report by ECHA (2015a) estimated 50–100 tonnes of a PFOA-related compound (CAS No: 70969-47-0, C_8-C_{20}-ω-perfluoro telomer thiols with acrylamide) within foam concentrates present across Europe in 2014. Australia (2018) comments that Australia has never manufactured PFOA or its precursor APFO, but import of fire-fighting concentrates included 48 grams and 0.6 grams of PFOA in 2002 and 2003 respectively. Other estimates include the FFFC (2018) inventory of PFOS assuming similar order of magnitude for PFOA based concentrates as 3.3 million gallons (12.5 million litres) of aqueous film forming foam (AFFF) PFOA based foams. Norway (2007) highlight a global inventory of APFO (the ammonium salt of PFOA, which was the main species used intentionally for fire-fighting foams) with production of 3,600–5,700 tonnes between 1951 and 2004. This can be back calculated to between 309 million and 4901 million litres of APFO based AFFF concentrate within existing stockpiles depending on the assumed shelf-life of the goods. Alternatives to all uses of PFOA in fire-fighting foams exist and include fluorine-free solutions as well as fluorosurfactants with C_6-fluorotelomers.[4]

17. IPEN and ACAT (2018) note reference to a number of fluorine free alternatives which have been tested as effective against Class B fires. Overall the costs associated with destruction and replacement can be perceived to be significant, one estimate by Seow (2013) quotes $1 AUD/ 1.5 Euro per litre of concentrate. However, costs associated with clean-up for sites contaminated by perfluorinated compounds are also significant, with examples quoted in the RME as millions of euros per site. IPEN (2018) commented that the life span of foams varied depending on climate and storage and therefore a 20-year derogation would not be acceptable for the Stockholm Convention. The FFFC (2016) state that foams do not have an expiry date but have a shelf life of 10–25 years.

18. Based on the information compiled and reviewed within the RME, the size of in-use stockpiles may be significant and socio-economic impacts of an immediate ban may be equally significant, potentially justifying a time-limited exemption. However, the impacts of release to ground water and socio-economic costs of clean-up are equally if not more significant, and the continued dispersive use of a POP is not consistent with the objectives of the Convention. On the other hand, the use of fluorinated alternatives could lead to contamination of water from short-chain PFAS, which is even more difficult to remediate than the contamination from the long chain ones. Concerning PFOA and PFOA-related compounds present as by-products in fluorotelomers based AFFF fire-fighting foams, the evidence reviewed suggests that they can be present at high concentration. The Committee should discuss if the non-fluorinated alternatives already commercialised and in use can replace the fluorine-based AFFFs for all uses and the issues surrounding existing stockpiles as two separate elements. On this basis, the Committee should consider a recommendation that covers both PFOA and PFOA-related compounds within fire-fighting foams and existing stockpiles.

Conclusion

19. Based on the review of information within the RME and elaborated on in the current document, only time-limited exemptions are envisaged. Furthermore, within the European restriction (EU 2017/1000) only one non-time limited exemption exists (implantable medical devices). MedTech (2018) commented that a transition period up to 2030 would be needed for implantable medical devices, suggesting that a time-limited exemption would be sufficient. Therefore, in accordance with paragraph 9 of Article 8 of the Convention, the Conference of the Parties to the Stockholm Convention should consider listing and specifying the related control measures of PFOA, its salts and PFOA-related compounds inin Annex A, with specific exemptions accompanied if needed with a specific part of Annex A that details actions.

[4] Note that Perfluorohexane-1-sulphonic acid (CAS No. 355-46-4) (PFHxS), its salts and PFHxS-related compounds have been nominated as a POPs and are currently under review by the Committee.

1 Introduction

1.1 Overview of actions to date

20. In June 2015, the European Union (EU) and its member States submitted a proposal to list pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds in Annex A, B, and/or C of the Stockholm Convention (UNEP/POPS/POPRC.11/5). This proposal was considered by the Persistent Organic Pollutants Review Committee (POPRC) at its eleventh meeting held in October 2015, where the Committee concluded that PFOA fulfilled the screening criteria in Annex D and that issues related to the inclusion of PFOA-related compounds that potentially degrade to PFOA and the inclusion of PFOA salts should be addressed in the draft risk profile (see decision POPRC-11/4).

21. The substances covered by the risk profile are PFOA including its isomers, its salts and PFOA-related compounds. At its twelfth meeting held in September 2016, by its decision POPRC-12/2, the Committee adopted the risk profile (UNEP/POPS/POPRC.12/11/Add.2) and decided to establish an intersessional working group to prepare a risk management evaluation dossier (RME) that includes an analysis of possible control measures for PFOA, its salts and PFOA-related compounds in accordance with Annex F to the Convention. Further, the Committee invited Parties and observers to submit to the Secretariat the information specified in Annex F before 9 December 2016.

22. By decision POPRC-13/2, the Committee adopted the RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2) and decided, in accordance with paragraph 9 of Article 8 of the Convention, to recommend to the Conference of the Parties that it consider listing PFOA, its salts and PFOA-related compounds in Annex A or B to the Convention with specific exemptions for the following:

(a) For five years from the date of entry into force of the amendment in accordance with Article 4:

(i) Manufacture of semiconductors or related electronic devices:

a. Equipment or fabrication plant related infrastructure containing fluoropolymers and/or fluoroelastomers with PFOA residues;

b. Legacy equipment or legacy fabrication plant related infrastructure: maintenance;

c. Photo-lithography or etch processes;

(ii) Photographic coatings applied to films;

(iii) Textiles for oil and water repellency for the protection from dangerous liquids for the protection of workers from risks to their health and safety;

(b) For ten years from the date of entry into force of the amendment for manufacture of semiconductors or related electronic devices: refurbishment parts containing fluoropolymers and/or fluoroelastomers with PFOA residues for legacy equipment or legacy refurbishment parts;

(c) For use of perfluorooctane iodide, production of perfluorooctane bromide for the purpose of producing pharmaceutical products with a review of continued need for exemptions. The specific exemption should expire in any case at the latest in 2036.

23. The Committee invited Parties and observers, including the relevant industries, to provide, by 12 January 2018, information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds in particular in the following applications:

(a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment: information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects;

(b) Transported isolated intermediates in order to enable reprocessing in another site than the production site: information on the quantities used, extent of transport and risks, and use;

(c) Medical devices: information on specific applications/uses and timelines foreseen as needed for potential related exemptions;

(d) Implantable medical devices: information on the quantities used, extent of transport and risks, and use;

(e) Photo imaging sector: information on paper and printing, and information relevant for developing countries;

(f) Automotive industry: information on spare parts;

(g) Firefighting foams: information on chemical composition of mixtures and the volumes of pre-installed amount of firefighting foam mixtures.

24. For the applications above, information regarding socio-economic aspects as well as other relevant information is also welcomed.

25. Furthermore, the Committee invited Parties and observers to provide, information that would assist the Committee to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds, in particular from primary aluminium production and from incomplete combustion. Finally, the Committee invited Parties and observers to provide information that would assist the Committee to further evaluate the chemical identity of PFOA-related compounds chemical list.

26. This document represents an *addendum* to the adopted RME of PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2; considering the information received from Parties and observers. The RME will not be re-opened. To aid readers, the present document contains references to the RME and repeats selected essential details from the RME (in italics) in order to enable a good understanding for an informed discussion at the fourteenth meeting of the Committee.

1.2 Structure of this document

27. For ease of reference this document has been set out in a chronological fashion to answer the questions set out by the Committee's invitation for additional information. Section 2 will provide an overview of information on substance identity. Section 3 will provide information on unintentional releases, and section 4 will provide information on each of the seven uses identified in paragraph 3 of decision POPRC-13/2. To provide as complete a narrative as possible and for ease of reference, where necessary sections of the RME have been included in the current document. Where this is the case, text will be marked in italics to clearly denote the text taken directly from the RME.

1.3 Data sources

28. The current document is primarily based on information that has been provided by Parties to the Convention and observers. Information was submitted by the following Parties:

(a) Parties: Belarus, Brazil, Canada, Ecuador, Monaco, Netherlands, Philippines, Sweden and United Kingdom of Great Britain and Northern Ireland (UK);

(b) Observers: Associação brasileira dos fabricantes de iscas inseticidas (ABRAISCA), FluoroCouncil (including Archroma), Canadian Vehicles Manufacturers' Association (CVMA), Fire-fighting Foam Coalition (FFFC), Health Care Without Harm (HCWH), MedTech Europe, and joint submission by International POPs Elimination Network (IPEN), and Alaska Community Action on Toxics (IPEN/ACAT).

29. In addition to the above-mentioned references and comments received from Parties and observers, information has been used from additional open information sources as well as scientific literature (see list of references). The following key references were used as a basis to develop the current document:

(a) RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/7/Add.2);

(b) Supporting information related to the RME on PFOA, its salts and PFOA-related compounds (UNEP/POPS/POPRC.13/INF/6);

(c) Additional information in relation to the RME of PFOA, its Salts, and Related compounds; Prepared by ETH Zurich on behalf of the Swiss Federal Office for the Environment (FOEN), 2017;

(d) Non-exhaustive list of substances covered or not covered by the RME. (UNEP/POPS/POPRC.13/INF/6/Add.1).

2 Chemical identity of PFOA, its salts and PFOA-related compounds

30. The Committee invited Parties and observers to provide information that would assist its further evaluation of the chemical identity of PFOA-related compounds chemical list. Relevant information has been submitted by The Brazilian Ministry of Agriculture (Brazil, 2018) and ABRAISCA (2018) (Brazilian association of manufacturer of insecticides), Norway (2018), Mexico (2018), Austria (2018), Japan (2018), Canada (2018) Fluoro Council (FluoroCouncil, 2018a, 2018b), and IPEN/ACAT (IPEN/ACT, 2018). No additional information is available for submission from Canada on the chemical identity of PFOA except from the information already presented in the risk profile and RME (Canada, 2018).

2.1 Chemical identity according to the RME

31. The chemical identity and related details are outlined in section 1.1 of the RME.[5] The following paragraphs in italics are copied from the RME:

32. PFOA, its salts and PFOA-related compounds fall within a family of perfluoroalkyl and polyfluoroalkyl substances (PFASs). Perfluorinated acids, like PFOA, are not degradable in the environment and in biota (including humans). Certain polyfluorinated substances can be degraded to persistent perfluorinated substances like PFOA. Those PFASs that can be degraded to PFOA in the environment and in biota are referred to as PFOA-related compounds.

33. The RME covers:

(a) PFOA (pentadecafluorooctanoic acid, CAS No: 335-67-1, EC No: 206-397-9) including any of its branched isomers;

(b) Its salts, and

(c) PFOA-related compounds which, for the purposes of this risk management evaluation, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C_7F_{15})C as one of the structural elements, for example:

(i) Polymers with ≥C_8 based perfluoroalkyl side chains;[6]

(ii) 8:2 fluorotelomer compounds;

(iii) 10:2 fluorotelomer compounds.

The compounds below do not degrade to PFOA and are therefore <u>not</u> included as PFOA-related compounds:

(i) C_8F_{17}-X, where X= F, Cl, Br;

(ii) Fluoropolymers[7] *that are covered by $CF_3(CF_2)n$-R', where R'=any group, n>16;*[8]

(iii) Perfluoroalkyl carboxylic and phosphonic acids (including their salts, esters, halides and anhydrides) with ≥8 perfluorinated carbons;

(iv) Perfluoroalkane sulfonic acids (including their salts, esters, halides and anhydrides) with ≥9 perfluorinated carbons;

(v) Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) as listed in Annex B to the Stockholm Convention.

Sulfluramid (*N*-ethyl perfluorooctane sulfonamide, CAS No: 4151-50-2) is <u>not</u> included as PFOA-related compounds since it is produced from PFOSF and it is then already covered under the listing of PFOS, its salts and PFOSF.

34. To assist the identification of PFOA-related compounds a non-exhaustive list of substances covered or not covered by the RME is provided in UNEP/POPS/POPRC.13/INF/6/Add.1. Sulfluramid is listed, but is explicitly excluded from the scope of the RME.

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[5] UNEP/POPS/POPRC.13/7/Add.2.

[6] DuPont, 1998. Technical information: Zonyl fluorochemical intermediates.

[7] Fluoropolymers have a carbon-only polymer backbone with F directly attached to backbone C atoms.

[8] Such as PTFE (polytetrafluoroethylene), FEP (fluorinated ethylene propylene polymer) and PFA (perfluoroalkoxy polymer).

2.2 Possible exclusion of sulfluramid from the scope of the RME

35. Sulfluramid is manufactured by using PFOSF as an intermediate and is the active ingredient in the manufacture of ant baits and ready-to-use formulations. The use of sulfluramid represents a direct release of PFOS to the environment. Sulfluramid is identified as a (potential) precursor of PFOAs in the OECD New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs). Brazil has notified the production and use of PFOSF for the acceptable purpose "insect baits for the control of leaf-cutting ants from *Atta spp.* and *Acromyrmex spp*".[9] Regarding baits used in Brazil, baits with sulfluramid represent more than 95% of the total use (UNEP/POP/POPRC.4/15/Add.6).

36. According to Brazil (2018), sulfluramid should be excluded from the list of PFOA-related compounds until conclusive information has been obtained. The main concern expressed is that sulfluramid is a compound related to PFOS, it salts and PFOSF and the use of this substance is already covered by the Stockholm Convention as acceptable purpose in Annex B (decision SC-4/17). However, the listing of PFOS and PFOSF in Annex B refers only to an "intermediate in the production of chemicals" and does not explicitly name sulfluramid or provide its CAS number. Brazil states that, the information regarding sulfluramid is consolidated as part of the process for evaluation of the continued need of PFOS, it salts and PFOSF for the various acceptable purposes and specific exemptions in accordance with paragraphs 5–6 of part III of Annex B to the Convention. Further, Brazil (2018) states that the inclusion of the substance in the PFOA list took place without extensive discussion and with no technical justification and that papers were cited as justification for the inclusion, which would not be conclusive and would not reflect the conditions that occur in the environment. It would therefore not be possible to conclude, based on this information only, that sulfluramid degrades to PFOA, nor that sulfluramid is a PFOA-related compound (Brazil, 2018).

37. The exclusion of sulfluramid from the non-exhaustive list of substances is also supported by ABRAISCA (2018), stating that sulfluramid is a perfluoalkyl sulfonate compound, and not a perfluoroalkyl carboxylate such as PFOA. Thus, according to ABRAISCA, sulfluramid should be in the list of compounds that do not degrade to PFOA. It is known that sulfluramid could be a PFOS-related compound and that the production of sulfluramid is obtained from PFOSF.

38. Martin et al. (2006) investigated the possibility that perfluorooctane sulfonamides which are present in the atmosphere may, via atmospheric transport and oxidation, contribute to perfluorocarboxylic acid (PFCA) and PFOS pollution in remote locations. According to the authors, their results suggest a plausible route by which perfluorooctane sulfonamides may serve as atmospheric sources of PFCAs, including PFOA (Martin et al. 2006). According to ABRAISCA, results from Martin et al. (2006) do not represent atmospheric conditions. In addition, ABRAISCA criticised that *N*-ethyl perfluorobutane sulfonamide was used as target material to investigate the gas phase reactivity of perfluoroalkane sulfonamides in the presence of radicals, and not the relevant substance, which has a different volatility (see ABRAISCA, 2018). However, the butane analogue, *N*-ethyl perfluorobutane sulfonamide, was used because *N*-ethyl perfluorooctane sulfonamide is not volatile enough for their in vitro system, but is an appropriate model because the perfluorinated chain length is not expected to have an effect on the reactivity. Even if the experimental conditions were not representative for environmental conditions, Martin et al. (2006) provide scientific evidence that the degradation of perfluorooctane sulfonamides to PFOA cannot be excluded. The results of D'eon et al. (2006) indicate that *N*-methyl perfluorobutane sulfonamidoethanol may contribute to the burden of perfluorinated contamination in remote locations. It appears that anthropogenic production of *N*-methyl perfluorooctane sulfonamidoethanol contributes to the ubiquity of perfluoroalkyl sulfonate and carboxylate compounds in the environment (D'eon et al., 2006). According to ABRAISCA, the results from this study investigating the formation of PFCAs from *N*-methyl perfluorobutane sulfonamidoethanol cannot be transferred to perfluoroalkane sulfonamides (such as sulfluramid), which have no hydroxyethyl group attached to a nitrogen atom. According to ABRAISCA this hydroxyethyl group leads to a higher reactivity compared to *N*-alkyl perfluoro sulfonamides (ABRAISCA, 2018). Even if the hydroxyethyl group in *N*-methyl perfluorobutane sulfonamidoethanol leads to a higher reactivity compared to *N*-alkyl perfluoro sulfonamides, it cannot be excluded that PFCAs are formed from *N*-alkyl perfluoro sulfonamides.

39. Plumlee et al. (2009) irradiated selected perfluorinated surfactants in aqueous hydrogen peroxide solutions using artificial sunlight to study transformation under aquatic environmental conditions, however, the study authors note that conditions simulated natural sunlight and that the relatively high peroxide concentration was only used to observe significant decay during the experimental time period. Indirect photolysis mediated by hydroxyl radical was among others observed for sulfluramid. ABRAISCA noted with regard to the study by Plumlee et al. (2009), that the conditions used in the study do not represent environmental conditions. Further, ABRAISCA stated that the formation of perfluorooctane sulfonamide from sulfluramid is by far more favourable than the formation of PFOA (see ABRAISCA, 2018). Moreover, ABRAISCA argues that sulfluramid molecules are not identical to *N*-methyl

[9] See register of acceptable purposes available at http://chm.pops.int/Implementation/Exemptions/AcceptablePurposes/AcceptablePurposesPFOSandPFOSF/tabid/794/Default.aspx.

perfluorobutane sulfonamidoethanol. Even if the experimental conditions were not representative for environmental conditions, Plumlee et al. (2009) provide scientific evidence that the degradation of sulfluramid to PFOA cannot be excluded.

40. Liu et al. (2017) analysed PFOS and PFOA release into the environment in the central and eastern region of China, which accounts for the vast majority of national emissions. According to the authors, sulfluramid likely resulted in the release of PFOS and PFOA to the environment. The environmental release of PFOS has been estimated to be 2.6 t/a while the release of PFOA from this source was calculated to be 1.4 t/a based on the annual consumption of sulfluramid, and the transformation rate to PFOA and PFOA content as impurities in sulfluramid (Liu et al., 2017). Regarding this study, ABRAISCA claimed that PFOS and PFOA are not present as contaminants in sulfluramid provided that it is synthesized by applying correct experimental procedures. Additionally, ABRAISCA mentioned that annual emissions of PFOS and PFOA from sulfluramid-based pesticides are overestimated and that data regarding degradation rates are missing. Further ABRAISCA stated that no new experimental scientific evidence is presented and that the study should be seen as a modeling paper to estimate emissions (see ABRAISCA, 2018). However, PFOSF is used to manufacture sulfluramid and when electrochemical fluorination is used to make PFOSF, there are a significant number of organic and inorganic by-products (Lehmler et al. 2007). The Liu et al. study also notes the possibility that the active ingredient in sulfluramid baits, *N*-ethyl perfluorooctane sulfonamide, can transform to PFOA and PFOS through photolysis, oxidation, and biotransformation indicating that PFOA release can occur in other ways besides impurities in sulfluramid.

41. Regarding the comments from ABRAISCA (2018) with respect to the question whether sulfluramid is a PFOA-related compound, it can be stated that two in vitro studies (Martin et al., 2006 and Plumlee et al., 2009) provide scientific evidence that indicates that sulfluramid can degrade to PFOA and could thus be considered a PFOA-related compound. Moreover, abiotic degradation to PFOA via photo-oxidation may occur given that volatilization of sulfluramid from moist soil surfaces is expected to be an important fate process (HSDB database) Austria added that in a recent report by the Norwegian environment Agency it was concluded that photooxidation of perfluorobutane sulfonic acid (PFBS) and perfluorohexane sulfonic acid (PFHxS) sulfonamides will also result in the release of C_2–C_6 PFCAs and concluded that the same mechanism can be anticipated for *N*-ethyl perfluorooctane sulfonamide. These studies and information sources suggest that a transformation of sulfluramid to PFOA is possible. However, the question whether sulfluramid can degrade to PFOA under environmental conditions is not conclusively clarified.

42. Sulfluramid is more structurally related to PFOS (both consist of a $C_8F_{17}SO_2$-unit) than to PFOA, thus degradation of sulfluramid to PFOS is more likely. Zabaleta et al. (2018) investigate the importance of sulfluramid as a source of environmental PFOS. The authors conclude on the one hand, that observed formation of PFOA may be due to the presence of *N*-ethyl perfluorooctanamide, which is known to occur as an impurity in sulfluramid. Zabaleta et al. (2018) performed experiments in the presence of carrot that produced PFOS yields of up to 34 % using a technical sulfluramid standard and up to 277% using a commercial sulfluramid formulation used in Brazil. The authors note that a significant fraction appears to be associated with one or more unidentified PFOS-precursors in the commercial bait. According to the authors, the data suggest that in the natural environment (and in particular in the presence of a vegetable crop), yields of PFOS from sulfluramid may be considerably higher than 4%. Avendaño and Liu (2015) reported 4% PFOS yields from degradation of EtFOSA from soil biodegradation experiments.

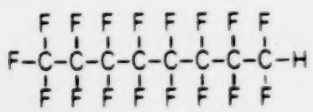
43. ABRAISCA (2018) provided information about a new study that is currently prepared by the Stockholm Convention Regional Center (CETESB) and the Brazilian Agricultural Research Corporation (Embrapa) with the aim to verify the degradation of sulfluramid in representative soils of reforestation areas in order to determine the transformation to PFOS. ABRAISCA argues that information about the transformation of sulfluramid into PFOS is scarce, in particular for soils in Brazil or tropical environments (ABRAISCA 2018). ABRAISCA argues that the statement that the use of insect bait may represents a release of PFOS in the environment lacks scientific evidence and that more information is needed. ABRAISCA informed that they are working with the Universidade Estadual Paulista "Júlio de Mesquita Filho" on the following project: "Assessment of the behaviour and degradation of Sulfluramid, applied in the form of ant bait for the control of leaf-cutting ants, in Brazilian soils" (ABRAISCA, 2018).

44. Sulfluramid is manufactured by using PFOSF (CAS No: 307-35-7) as an intermediate. From a structural point of view, sulfluramid is related to PFOS (CAS No: 1763-23-1) and degrades in the environment to PFOS (Nguyen et al. 2013, Avendano and Liu 2015, Beskin et al. 2009, Gilljam et al. 2015). Based on the available information sulfluramid could also be considered a PFOA-related compound. PFOSF (restricted under the listing of PFOS, its salts and PFOSF according to Annex B to the Stockholm Convention) is used to produce sulfluramid, then used for control of leaf-cutting ants from *Atta spp.* and *Acromyrmex spp.* as well as insecticides for control of imported red fire ants and termites. However, sulfluramid is not explicitly included the scope of the listing of PFOS, its salts and PFOSF. Therefore, we can consider that sulfluramid production is already covered by an acceptable purpose under the PFOS listing and it should then not be included under the PFOA listing to avoid double regulation.

2.3 Possible exclusion of 1-H-PFO from the scope of the RME

45. The status of 1-H-PFO (1-hydroperfluorooctane, PFOH, CAS No: 335-65-9) as a PFOA-related compound is questioned by FluoroCouncil (FluoroCouncil, 2018a). Currently, substances with the formula C_8F_{17}–X are considered PFOA-related compounds except if the X consists in either fluorine, chlorine or bromine (i.e. C_8F_{17}-F, C_8F_{17}-Cl or C_8F_{17}-Br) ending or they are specifically excluded from the scope (e.g. PFOS) As a result, 1-H-PFO is considered a PFOA-related compound. FluoroCouncil (2018) argues that C_8F_{17}-H (1-H-PFO) is even less accessible to biological and chemical degradation compared to the exempted molecules C_8F_{17}-Cl and C_8F_{17}-Br. FluoroCouncil further states that 1-H-PFO has comparable temperature and chemical inertness to the fully fluorinated perfluorooctane C_8F_{18} and that the C_8F_{17}-H structure and excellent thermal stability which shows no evidence of degradation to PFOA under foreseeable conditions. 1-H-PFO's transformation into PFOA would require the loss of the hydrogen as well as two Fluor atoms on the carbon (see Figure 2.1). FluoroCouncil states that this has never been observed considering the remarkable stability of the C-F bond and the fact that the hydrogen is surrounded by 3 large atoms of Fluor (FluoroCouncil, 2018a).

1-H-PFO chemical formula (C8F17-H)



PFOA chemical formula (C7F15-C(=O)OH)

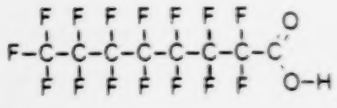


Figure 2.1 chemical structure of 1-H-PFO and PFOA

46. FluoroCouncil argues that 1-H-PFO should not be considered a PFOA-related compound (see section 4.3 on transported isolated intermediates). FluoroCouncil believes that the scientific basis for the status of 1-H-PFO as PFOA-related compound should be further investigated (FluoroCouncil, 2018a). Japan brought forward that it would be an overstatement to conclude that 1-H-PFO is among PFOA-related compounds because the reaction rate with OH radicals is negligibly small at the order of 10E(-15)cm^3 molec-1 s-1 (Japan, 2018).There is some evidence that 1-H-PFO is relatively stable. The bond dissociation energy of C-H is 338 kJ/mol (for C-Cl it is C-Cl 395 kJ/mol and 318 kJ/mol for C-Br) (Luo, 2007).[10] However, Chen et al. (2003) showed that $CF_3CF_2CF_2CF_2CF_2CHF_2$ can react with OH radicals over the temperature range -23 to 156°C (reported in Chen et al. as Kelvin: 250-430 K). This shows for a shorter-chained hydrofluorocarbon (HFC) compound with a -CHF_2 moiety that a H-abstraction reaction by OH radicals takes place and the carbon-oxygen bond degrades. Young et al. (2009) showed that PFCAs can be formed from atmospheric reactions of CF_3CF_2H and $CF_3CF_2CF_2CF_2H$ in absence of NOx. Accordingly, HFCs with the –CHF_2 moiety (e.g., HFC-329ccb and HFC 52-13p) can react with OH radicals and form a perfluoroalkyl radical ($CF_3(CF_2)n•$),which can further react to form PFCAs (under low NO_x conditions) (see Wang et al. 2014). Chen et al. (2011)[11] propose a mechanism for the oxidation of 1-H-PFO to PFOA in the atmosphere through reaction with OH radicals. They report that molar yields of PFOA range between 0.07-0.12. These results suggest that a transformation from 1-H-PFO to PFOA is possible. Specific data for the transformation of 1-H-PFO to PFOA is not available. The FluoroCouncil argues that the intramolecular shielding of the H-C bond makes degradation extremely unlikely and that, in atmospheric conditions, the probability of a reaction with OH radicals is further reduced by the existence of a competing reaction with NOx that does not result in PFOA. However, Switzerland notes that 1-H-PFO remains in the atmosphere (> 99 % based on EPI Suite Level III Fugacity Model with emissions to air only) until transformed and 1-H-PFO may be transformed to PFOA over long time scales (Switzerland 2018). Chen et al. (2011) estimated an atmospheric lifetime of 24 year.

47. In conclusion, 1-H-PFO should be considered a PFOA-related compound since scientific evidence indicates that a transformation to PFOA is possible and should be included in the non-exhaustive list of PFOA-related compounds. In addition, 1-H-PFO is identified as a (potential) precursor of PFAAs in the OECD New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs).

[10] Luo, Y.R 2007 Comprehensive Handbook of Chemical Bond Energies. CRC Press, Boca Raton, FL, USA.

[11] Chen, L., Uchimaru, T., Kutsuna, S., Tokuhashi, K., Sekiya, A. and Okamoto, H. (2011). Kinetics and mechanism of gas-phase reaction of CF3CF2CF2CF2CF2CF2CF2CF2H with OH radicals in an environmental reaction chamber at 253–328K. Chemical Physics Letters, 501(4-6), pp.263-266.

2.4 Inclusion of 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate in the scope of the RME

48. Based on information submitted by Australia (2018), 8:2 fluorotelomer methacrylate (CAS No: 93705-98-7), polymer with methyl methacrylate should be included in the non-exhaustive list of PFOA-related compounds. Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS) under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework concluded that PFOA is expected to be the major product of environmental biodegradation for the following five long-chain fluorinated chemicals on the Australian Inventory of Chemical Substances (AICS) (NICNAS undated): 8:2 fluorotelomer alcohol (CAS No: 678-39-7), 8:2 fluorotelomer methacrylate (CAS No: 1996-88-9), 8:2 fluorotelomer methacrylate, polymer with methyl methacrylate (CAS No: 93705-98-7); propanamide, 3-[(.gamma.-.omega.-perfluoro-C_{4-10}-alkyl)thio] derivatives (CAS No: 68187-42-8); and 7:1 fluoroalcohol methacrylate, polymer with acrylic acid (CAS No: 53515-73-4). The remaining 4 chemicals indicated are already included in the list of non-exhaustive substances.

49. In conclusion, 8:2 fluorotelomer methacrylate polymer with methyl methacrylate (CAS No: 93705-98-7) could be considered for inclusion in the non-exhaustive list of PFOA-related compounds. Further data related to main components by environmental degradation of polymer with methyl methacrylate would be supportive.

3 Information on unintentional formation and release

50. The Committee invited Parties and observers to provide information that would assist to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production. Relevant information in response to the request for information was submitted by IPEN and ACAT (2018), the Netherlands (2018a) and Austria (2018). The UK (2018) stated that PFOA is not a substance that is reported within the UK's Pollution Inventories, and therefore no relevant data on its releases is available. The same also applies to emissions from primary aluminium production (UK, 2018). No additional information (in addition to the already included in the RME) is available from Canada (Canada, 2018).

3.1 Unintentional formation and release from incomplete combustion

51. During the development of the RME, Switzerland supplied information on unintentional formation of PFOA from incineration of fluoropolymers with inappropriate incineration or open burning facilities at moderate temperatures. Recent studies have been summarized, *showing measurable amounts of PFOA and a wide range of other PFCA homologues that can be generated during the thermolysis of PTFE (polytetrafluoroethylene) at temperatures between 250 and 600°C. It has been concluded that this may be particularly relevant for developing countries and countries in transition, where wastes are often not incinerated to sufficiently high temperatures and without proper treatment of flue gases* (FOEN, 2017).

52. *High temperature incineration (e.g., at 1000°C) can be effective to destroy PFOA and to prevent the formation of PFOA from the thermolysis of highly fluorinated polymers. It is however, currently unclear to what extent formation of PFOA may occur in municipal waste incinerators where (1) flue gases may reach temperatures of 850°C or greater and may result in different degradation products; (2) other substances coexist and may interfere with the thermolysis of fluoropolymers (e.g., thermolysis of PTFE is inhibited by a hydrogen or chlorine atmosphere in contrast to steam, oxygen or sulfur dioxide, which accelerate decomposition; and (3) technologies such as activated carbon injection (ACI) coupled with baghouse filtration (BF) may be installed to remove dioxin or mercury and may also trap PFCAs.* A laboratory-scale study from the US concluded that waste incineration of fluorotelomer-based polymers does not lead to formation of detectable levels of PFOA under conditions representative of typical municipal waste incineration in the US. However, *a recent study found PFOA in flue gases from a state of the art incinerator of Harlingen, the Netherlands* (see the RME). Currently (as of 2018) PFOA is not regulated as an air pollutant from waste incineration under the Industrial Emission Directive (Directive 2010/75/EU) on European level (Austria, 2018). In Europe, the state of the art (best available technique, BAT) in waste incineration is defined in the European BAT Reference Document on Waste Incineration (BREF WI 2006), issued by the European IPPC Bureau (EIPPCB) in 2006. The document has been subject to a review process since July 2014, which is supposed to be finished by the end of 2018. In contrary to for instance polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/PCDF) and PCBs, PFOA and other fluorinated and/or brominated organic compounds are not addressed by the BREF WI so far (POPRC Member, 2018).

53. Information provided by IPEN and ACAT (2018) in their current submissions mainly supports information provided by Switzerland which has already been considered in the RME, and further includes additional information on PFOA detected in a state of the art incineration facility in the Netherlands (Harlingen). According to information provided by IPEN and ACAT (2018), PFOA can be unintentionally generated as a product of incomplete combustion arising from open burning and waste incineration processes. In laboratory experiments, high temperature incineration is effective to destroy PFOA and prevent formation of PFOA, however, in practise PFOA may be formed in currently operating incinerators (a link to raw data from the above-mentioned incinerator in Harlingen has been provided as

reference).[12] IPEN and ACAT (2018) conclude that stringent adherence to best available techniques and best environmental practices (BAT/BEP) is needed to avoid PFOA generation and release and that PFOA should be listed in Annex C as an unintentional POP to capture potential formation and unintentional release from anthropogenic sources (IPEN and ACAT, 2018). Further, according to information provided by Austria (2018), there is evidence given in literature from the Netherlands that flue gas from waste incineration also contains brominated flame retardants, polybrominated diphenyl ethers and PFOA. Under unstable conditions polybrominated dibenzo-*p*-dioxins and dibenzofurans (PBDD/PBDFs) were also found.[12] There is also evidence from laboratory experiments that fluoropolymers have to be regarded as possible sources of halogenated organic compounds generated during waste incineration.[13]

54. According to the recent submission by the Netherlands (2018a), listing PFOA in Annex C to the Convention is not recommended due to the following reasons. Firstly, the data from the Harlingen municipal waste incinerator from the Netherlands indicates that PFOA emissions are negligible. Estimating a yearly emission, using the flow rate of the installation, the total PFOA emission is shown to be 0.057 g/yr (at concentrations about 0.01–0.04 ng/m^3). Compared to the amounts mentioned in other places in this document (most are in kg's or tonnes) this amount is negligible and the costs to monitor and reduce the emissions are disproportionate. Furthermore, emissions of other POPs such as decabromodiphenyl ether (decaBDE) are in a similar order of magnitude and indicate that all POPs may be expected in all kinds of incineration processes, which is also related to the fact that measurement techniques have improved considerably in recent decades. According to the Netherlands, these reasons need to be considered to enable the COP to properly evaluate the pros and cons of a possible Annex C listing (Netherlands, 2018).

3.2 Unintentional formation and release from primary aluminium production

55. According to the RME, referring to a study from the EU Parliament from 2008, perfluorocarbons (PFCs) are widely used in aluminium production and emissions of PFCs (possibly including PFOA; not specified in the study) occur during specific electrolysis processes in aluminium manufacturing.[14] This can be reconfirmed by several information sources, for instance Gibbs et al. (2001) stating that the primary aluminium production process has been identified as the largest anthropogenic source of emissions of two PFCs: tetrafluoromethane (CF_4) and hexafluoroethane (C_2F_6). It is further explained that primary aluminium is produced using the Hall-Héroult electrolytic process, where the smelting pot itself acts as the electrolysis cell during the reduction process. When the alumina ore content of the electrolytic bath falls below critical levels required for electrolysis, rapid voltage increases occur, termed "anode effects". Anode effects cause carbon from the anode and fluorine from the dissociated molten cryolite bath to combine, producing CF_4 and C_2F_6. Further, the International Aluminium Institute provides among other statistics, information on global PFCs emissions from aluminium production. The available data refers to emissions of gases containing CF_4 and C_2F_6.[15] It was not possible to identify relevant information indicating that also PFOA may be released from aluminium production. It seems that most of the available information relates to emissions of CF_4 and C_2F_6 from aluminium production. No additional information has been submitted by Parties and observers on potential releases of PFOA from aluminium production.

3.3 Summary and conclusion related to unintentional formation and release

56. In summary, the Committee invited Parties and observers to provide additional information to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production. New information was provided by IPEN and ACAT (2018), the Netherlands (2018a) and Austria (2018). The UK (2018) stated that PFOA is not a substance that is reported within the UK's Pollution Inventories, and therefore no relevant data on its releases is available. The same also applies to emissions from primary aluminium production (UK, 2018).

57. Information from the RME indicates that *PFOA may be unintentionally formed and released from inadequate incineration or open burning at moderate temperatures*. Switzerland provided recent studies (FOEN, 2017), showing small, but measurable amounts of PFOA detected at incineration temperatures between 250 °C and 600 °C. Therefore, it has been concluded that this may be particularly critical for developing countries and countries in transition, where wastes are often not incinerated to sufficiently high temperatures and without proper flue gas treatment. The submissions from IPEN and ACAT (2018) are in line with information submitted by Switzerland and further include information on PFOA detected in a state of the art incineration facility in the Netherlands (at concentrations about 0.01–0.04 ng/m^3). IPEN and ACAT (2018) conclude that stringent adherence to BAT/BEP techniques is needed to

[12] www.harlingen.nl/recloket and https://www.harlingen.nl/recloket/monitoring-in-de-schoorsteen_42638//.

[13] Ellis et al. (2001): Ellis, D.A., et al. "Thermolysis of fluoropolymers as a potential source of halogenated organic acids in the environment. "Nature Vol. 142, 19 July 2001, www.nature.com (2001)).

[14] http://www.europarl.europa.eu/RegData/etudes/etudes/join/2008/393524/IPOL-ENVI_ET(2008)393524_EN.pdf.

[15] http://www.world-aluminium.org/statistics/perfluorocarbon-pfc-emissions/.

avoid PFOA generation and release and that PFOA should be listed in Annex C as an unintentional POP. The Netherlands (2018a), in contrast, indicates that adding PFOA to Annex C is not the right way forward as estimated yearly emissions, appear to be negligible, and costs to reduce the emission are disproportionate. Further, it is pointed out by the Netherlands (2018a) that other POPs (such as decaBDE) are detected in a similar order of magnitude as PFOA, without currently being listed under Annex C.

58. No information has been submitted by Parties and observers on potential releases of PFOA, its salts and PFOA-related compounds from primary aluminium production.

59. In conclusion, available information to further evaluate unintentional formation and release of PFOA, its salts and PFOA-related compounds from incomplete combustion and primary aluminium production is limited. There is a contradicting opinion among Parties and observers on the possible listing of PFOA in Annex C. Additional information and preferably also further measurements / quantitative data from other waste incinerators, open burning, and other sources of unintentionally produced POPs would be useful for further discussion on this topic (e.g. at POPRC14). For potential PFOA releases from aluminium production, most of the information identified in literature relates to emissions of CF_4 and C_2F_6 during aluminium production. From the currently available information it is not possible to conclude that primary aluminium production represents a relevant source of PFOA releases to the environment.

4 Uses of PFOA, salts and PFOA-related compounds where further exemptions may be needed

4.1 Introduction

60. The RME identified a range of uses[16] covering applications for production of fluoropolymers (primarily polytetrafluoroethylene (PTFE)), use as surfactants and one use involving the generation of intermediates for further processing. All seven of the uses documented in the RME have the potential to generate releases during production, use and end of life for articles. During POPRC-13 in October 2017, the Committee discussed each of these uses and whether an exemption was necessary, but were unable to reach a conclusion. The Committee invited Parties and observers to provide further information around specific aspects of each use (see section 1.1) which are presented in the current document.

61. Existing national and regional control actions differ with regard to their chemical scope and exemptions. Appendix I to this document (Table 3 of the RME) gives an overview of the regulatory risk management approaches and exemptions in Canada, the EU and Norway. Section 3 of the background document (UNEP/POPS/POPRC.13/INF/6) provides further details on the legislative approaches in these countries.

4.2 (a) Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment

4.2.1 Introduction

62. The RME highlights the need for more information about a possible exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment. Additional information to clarify the scope of the applications, used amounts, availability of alternatives and socio-economic aspects is needed to allow for an exemption.

63. The Committee invited Parties and observers to submit further information on the scope of the applications, used amounts, availability of alternatives, socio-economic aspects and other relevant information. Information on membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment has been provided by Canada (2018), China (2018), Mexico (2018) and IPEN and ACAT (2018). Furthermore, additional information has been identified in the submissions from HealthCare Without Harm Europe (HCWH, 2018) and MedTech Europe (2018), providing information related to medical devices.

[16] A number of the uses covered have applications in healthcare. The RME disaggregates healthcare uses based on different applications, for example membranes covers all uses of PFOA within membranes, some of which will include medical applications. To maintain this distinction uses relating to healthcare can be found under the following headings by application, section 4.2 for membranes, section 4.6 for photo-imaging, section 4.5 for implantable medical devices and section 4.4 for all other medical devices.

4.2.2 Efficacy and efficiency of possible control measures

64. According to IPEN and ACAT (2018), the use of PFOA should be specifically identified to enable consideration of a specific exemption. IPEN and ACAT (2018) therefore conclude that no exemption for PFOA use in membranes for filtration in water treatment, production processes and effluent treatment should be recommended, since no specific use has been named in the evaluation process. The same has been also concluded for application in medical textiles (IPEN and ACAT, 2018).

65. A possible presence of PFOA in surgical drapes was confirmed by MedTech: "The presence of PFOA is mainly related to the use of fluoropolymers such as PTFE" (MedTech Europe, 2018). According to information submitted by HCWH (2018), PFOA can be found in several products in health care including textiles. A complete picture on PFOA use in the sector is however not yet available. For this reason, HCWH believes that it is crucial as a first step to collect further information and determine which fluorinated compounds are present in products used in the healthcare sector (HCWH, 2018).

66. According to information submitted by Canada (2018), commercial filter membranes can be made of different materials, some based upon fluorochemicals such as polyvinylidene fluoride (PVDF), poly(ether sulfone) (PES) and polytetrafluoroethylene (PTFE). PFOA can be used as a surfactant in the emulsion polymerization of PTFE. Further, according to Canada, PTFE membranes are among others used in manufacture of purified water and special need water, beverage and dairy, chemical regent, biochemical regent, air filtration of fermentation tank, purification and filtration in microelectronic plants, filtration and separation of antibacterial fluid, production of medicine, air conditioning of hospitals and commercial buildings (Canada, 2018).

4.2.3 Information on alternatives

67. The companies Arkema, Asahi, BASF Corporation, Clariant, Daikin, 3M/Dyneon, DuPont and Solvay Solexis have agreed under the US EPA 2010/15 Stewardship program to manufacture fluoropolymers without using PFOA (as processing aid) by the end of 2015. The objective of the proposal is to restrict the placing on the market, import, and use of fluoropolymers manufactured with PFOA, while allowing the use of the same fluoropolymers when they are not manufactured with PFOA. The substitution was reportedly being carried out by around 70% of the global market for fluoropolymers in 2015 (ECHA, 2014a).

68. According to the RME, *for filter materials for oil and fuel filtration some companies claim that no alternatives are available*. This has been also stated in a recent submission from China (2018). However, it is also further stated that several strategies can be taken to use potentially non-bioaccumulable alternatives of PFOS and PFOA (China, 2018).

69. Several alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME. In the following paragraphs, relevant alternatives are briefly summarised (see the RME for full details, not for discussion).

Short-chain fluorinated alternatives

70. Information on short-chain fluorinated alternatives was identified in the RME. For the fluorotelomer products based on 8:2 fluorotelomer alcohol (8:2 FTOH), short-chain 6:2 FTOH are used as alternatives for a variety of uses including textiles. This substance will not degrade to PFOA, but rather to other acids, such as perfluorobutanoic acid (PFBA), perfluoropentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA), and 2H,2H,3H,3H-undecafluoro octanoic acid (5:3 fluorotelomer acid). The fluorinated chemical alternatives to PFOA (6:2 FTOH, PFHxA, 6:2 methacrylate and 6:2 acrylate) have not been evaluated under the Stockholm Convention. However, IPEN and ACAT highlight that there are several related scientific literature sources and conclude that these alternatives raise various concerns including persistence, long range transport, high mobility in water and soil and potential toxic properties. For instance, 6:2 FTOH is found in the Artic and the Antarctic, has endocrine disrupting properties, is found in indoor air, air of manufacturing plants, house dust, food contact materials and consumer products (based scientific literature studies). Besides, PFHxS is currently nominated and under review by the Committee (Canada, 2018). Concerns that short-chain fluorinated alternatives meet POP criteria are further addressed in the RME for instance in paragraph 179.

71. *During the development of the RME, industry associations noted that especially in the field of professional, technical and protective textiles and other advanced textiles, no alternatives meeting the high demand by legal requirements and by customers are currently available. However, those textile products that must only fulfil low-performance requirements, which were formerly treated with PFOA-related compounds, may be treated by C_6-products or even fluorine-free alternatives* (see the RME).

72. *The European Apparel and Textile Confederation states that over the life-cycle, technical textiles treated with 6:2 fluorotelomer-based finishes often exhibit 4–8 times higher total PFAS emissions compared to the observed emissions using the C_8-chemistry* (see the RME).

Non-fluorine-containing alternatives

73. According to the RME, *non-fluorine containing alternatives in the textile industry include paraffins, alpha olefin modified siloxanes, fatty-acid modified melamine resins and fatty-acid modified polyurethanes exist for textiles with low required levels of water repellency. In some cases, when applying fluorine-free alternatives, quality requirements of technical textiles cannot be fulfilled due to, for example, decreased chemical-, oil- and/or dirt-repellent properties, inadequate abrasion and/or wash resistance. Available alternatives for grease- and dirt-repellent agents are limited. Most prominent water-repellent alternatives are reported to be silicone-based agents. These include high molecular weight polydimethylsiloxanes (PDMS), mixtures of silicones and stearamide methyl pyridén chloride (sometimes in combination with carbamide (urea) and melamine resins), waxes and paraffins (usually consisting of modified melamine-based resins) and dendrimers that are being developed to imitate the ability of the lotus blossom to repel water. Alternatives to provide similar stain- and water-repellency are available and include textile surface treatment applications based on acrylate, methacrylate adipate and urethane polymers* (see the RME).

74. According to the RME, *a range of fluorocarbon-free, water-repellent finishing agents for textiles include commercial products such as BIONIC-FINISH® ECO and RUCO-DRY® ECO marketed by Rudolf Chemie Ltd., Geretsried Germany; Purtex® WR, Purtex® WA, Purtex® AP marketed by the Freudenberg Group, Weinheim Germany; and ecorepel® marketed by SchoellerTechologies AG, Sevelen Switzerland* (see the RME).

75. According to the RME, *paraffin repellents are liquid emulsions that should not be classified as hazardous to health according to the producers. However, some of the identified ingredients seem to be harmful. The main ingredient in most products is paraffin oil wax (mixtures of long chain alkanes), which is considered harmless in pure form. Some products also contain isocyanates, dipropylene glycol, metal salts, which may be harmful* (see the RME).

76. According to the RME, *PDMS are inert and have in general no adverse effects. Various siloxanes, especially the cyclic siloxanes known as D4, D5 and D6 and specific linear siloxanes are intermediates for the synthesis of silicone polymers used for textile impregnation. Certain siloxanes are persistent and widespread in the environment. Mostly, they are detected in urban areas and in the aquatic environment. High levels have been found in livers of fish, which were caught close to outlets of sewage treatment plants. Siloxanes are generally removed from the aqueous phase by sedimentation, and exhibit a long half-life in sediments. In soils, siloxanes are transformed depending on the conditions into hydroxylated forms, which still may be persistent. In Canada, it is concluded that D4 is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity* (see the RME). In Europe, D4, D5 and D6 are being considered for identification as Substances of Very High Concern (SVHCs) under the REACH regulation.

77. IPEN and ACAT (2018) submitted information that technically feasible alternatives that meet regulatory requirements but do not contain PFOA are available. These include surgical gowns and drapes.[17] [18] [19] [20] According to Wang et al. (2015) and Rudolf Group (2018), "non-fluorinated water-repellent textile finishes that are based on high molecular weight and highly branched polymers known as dendrimers have been commercialized" for use in textile pre-treatment, coating, sizing, and finishing and may have application for medical textiles.

78. According to the RME, *there are no data on health properties of the active substances and other components of dendrimer-based repellents, but producers of commercial products have provided health data in the material safety data sheets and made some proposals for classification of the product. According to information from producers these products should not be classified as harmful for the environment, but it is not possible to evaluate these statements on the basis of available information. The compositions of the products were not specified sufficiently for an assessment, but some of the products include unknown siloxanes, cationic polymers, isocyanates, or irritating organic acids. In summary, the available information for this group of chemicals is insufficient for an assessment of the possible health effects of the impregnation agents* (see the RME).

79. *The RME identified alternatives to PFOA for use in reverse osmosis membranes for water and effluent treatment. It notes that for membranes an alternative to PTFE is a composite of a hydrophobic polyester and a hydrophilic polymer forming a microstructure, which allows the fabric to breathe* (see the RME).

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[17] http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8l00xm8mI8t94y70k17zHvu9lxtD7xt1evSSSSSS-

[18] https://www.daikinchem.de/products-and-performance/water-oil-repellency

[19] https://products.halyardhealth.com/surgical-solutions/surgical-gowns/breathable-high-performance-gowns/halyard-microcool-breathable-high-performance-surgical-gown-with-secure-fit-technology.html

[20] https://www.agcchem.com/news/2016/june-1-2016-asahiguard-ag-e600-repellent-provides-sustainable-solution-for-nonwoven-medical-textiles

80. Syndar Filtration manufactures membranes for a wide variety of purposes, including water filtration, effluent treatment, production processes, and medical applications. They use fluorine-free materials for these applications including: polyacrylonitrile (PAN), most often used for oil/water separations and similar applications; polyethersulfone (PES), most often used for protein concentration and purification; and thin film composite (TFC), these membranes use PES with polyamide coatings that are used for various concentrating and purifying applications[21] (IPEN and ACAT, 2018).

Non-chemical alternatives

81. Considering information provided by IPEN and ACAT (2018), bioinspired slippery liquid-infused porous surfaces, based on substances found in the Nepenthes plant, although still in the development phase, have a broad application that includes biomedical devices, optical sensing, fluid/fuel handling, and anti-fouling; and provide a viable alternative for surface treatments.[22]

4.2.4 Information on impacts on society

82. According to the textile industry submissions, *the technical textile sector has to fulfil many different performance standards in particular medical, chemical and environmental protection. Textiles have to be certified in long procedures, which could take years and several textiles are regulated by various other EU- and national laws* (see the RME).

83. According to ECHA (2014), the introduction of alternatives in the fluoropolymers production industry has been carried out by around 70% of the global market which took place with a moderate price increase (see the RME).

84. IPEN and ACAT (2018) state in their recent submission, that prohibiting the use in these applications would have a positive impact on human health and the environment by limiting further PFOA releases and exposures and a positive impact on businesses making alternatives, particularly non-fluorinated alternatives.

85. Mexico (2018) would support a time-limited exemption for the membranes used in medical practices to prevent impact upon patients. However, no further information / justification has been given.

4.2.5 Synthesis of Information

86. According to HCWH (2018) and IPEN and ACAT (2018), membranes intended for use in medical textiles could include products that function as a barrier to exposure to blood or fluids such as surgical drapes, in which the presence of PFOA is mainly related to the use of fluoropolymers. However, they indicate that there are technically feasible alternatives available that meet regulatory requirements but which do not contain PFOA. These include surgical gowns and drapes.[23] [24] [25] [26]

87. According to information submitted by Canada (2018), PFOA can be used as a surfactant in the emulsion polymerization of PTFE. PTFE membranes are reported to be used in various applications (see e.g. Canada, 2018).

88. According to the RME, *for filter materials for oil and fuel filtration some companies claim that no alternatives are available*. Specific information is, however, not available.

89. According to the information available, technical and/or economically feasible alternatives exist for membranes intended for use in medical textiles and filtration in water treatment, production processes and effluent treatment. No specific application has been identified that requires C_8-chemistry.

90. IPEN and ACAT (2018) state that a prohibition on PFOA use for these applications would benefit companies making alternatives, particularly non-fluorinated alternatives. 70% of the fluoropolymer producing market has already replaced the use of PFOA by the end of 2015 at a moderate price increase (ECHA, 2014a). This indicates that

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[21] http://synderfiltration.com/ and personal communication with Kevin Donohue, Global Sales Manager, Syndar Filtration 9 January 2017.

[22] Wong, T-S et al. 2011. Bioinspired self-repairing slippery surfaces with pressure-stable omniphobicity. Nature 477:443-447.

[23] http://multimedia.3m.com/mws/mediawebserver?mwsId=SSSSSu9n_zu8l00xm8mlBl8t94v70k17zHvu9lxtD7xt1evSSSSSS-

[24] https://www.daikinchem.de/products-and-performance/water-oil-repellency.

[25] https://products.halyardhealth.com/surgical-solutions/surgical-gowns/breathable-high-performance-gowns/halyard-microcool-breathable-high-performance-surgical-gown-with-secure-fit-technology.html.

[26] https://www.agcchem.com/news/2016/june-1-2016-asahiguard-ag-e600-repellent-provides-sustainable-solution-for-nonwoven-medical-textiles.

membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment can possibly be produced without PFOA.

91. The Committee requested information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects. Information was submitted on the scope of the applications and the availability of alternatives by HCWH (2018), Canada (2018) and IPEN and ACAT (2018). IPEN and ACAT (2018) suggest that the socio-economic impacts of not allowing PFOA for these uses should be more limited given that feasible alternatives exist and are in use. Used amounts for specific applications and related information which would enable the socio-economic aspects and information on the possible non-availability of alternatives to be evaluated would be needed to further evaluate possible exemptions. In conclusion, more specific information on the scope of the applications, used amounts, non-availability of alternatives and socio-economic aspects is still lacking and the information reviewed does not substantially help to enable the Committee to evaluate whether there is a specific need for an exemption.

4.2.6 Conclusion

92. Based on the evaluation of available information, an exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment should not be considered.

4.3 (b) Use of perfluorooctane iodide (PFOI) as isolated intermediate in order to enable reprocessing to tetrafluoroethylene (TFE) and hexafluoropropylene (HFP) in another site than the production site

93. The RME for PFOA highlighted a potential need for more information about a possible exemption for transported isolated intermediates. An exemption without time limit is included in the EU restriction, paragraph 4(c) (EU 2017/1000 amending EC 1907/2006), provided that the use complies with the REACH definition of strictly controlled conditions according to Art. 18(4) (described further below). Therefore, the need for an exemption should be assessed under the Stockholm Convention to enable reprocessing at a different site than the production site. The conditions could be similar to what is established under the EU restriction, as quoted in the RME: *"(1) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage; (2) procedural and control technologies shall be used that minimise emission and any resulting exposure; (3) only properly trained and authorised personnel handle the substance; (4) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered; (5) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures; (6) substance-handling procedures are well documented and strictly supervised by the site operator"*.

94. The Committee invited Parties and observers to provide information that would assist the possible defining of specific exemptions, in particular for transported isolated intermediates, in order to enable reprocessing at a different site than the production site. The Committee requested information related to the quantities used, extent of transport and possible risks, and use.

95. Relevant information was submitted by IPEN and ACAT (2018), by the FluoroCouncil (2018), Norway (2018), and the Netherlands (2018a).

4.3.1 Efficacy and efficiency of possible control measures

96. An exemption should be considered under the Stockholm Convention with similar conditions to those established under the EU restriction (EU 2017/1000) approach. IPEN and ACAT (2018) note that the proposal to exempt transport of isolated intermediates at the global level undermines the integrity of the Stockholm Convention. The Convention limits generic exemptions relating to intermediates to strictly closed-system site-limited intermediates that are chemically transformed in the manufacture of other chemicals that, taking into consideration the criteria in paragraph 1 of Annex D, do not exhibit the characteristics of POPs.[27] However, exemptions for the transport of intermediates can still be requested.

97. An exemption to Daikin Industries Ltd for transported isolated intermediates has already been considered in the RME for the transport of PFOI (perfluorooctyl iodide, CAS No: 2043-57-4) that is *generated during the production of 6:2 fluorotelomer-based substances, whereby a fraction of the isolated intermediate PFOI is then transported to another site in Japan to produce PFOB*, used for pharmaceutical applications (see RME para 89 and 201).

[27] Note (iii) of Part I of Annexes A and B to the Stockholm Convention.

98. The FluoroCouncil (2018) submitted a request for an exemption for the "use of PFOI as intermediate in the production of TFE (tetrafluoroethylene, CAS No: 116-14-3) and HFP (hexafluoropropylene, CAS No: 116-15-4)". The FluoroCouncil provides information on the processes from their member, Archroma, on the research and development (R&D) activities, as well as the strict conditions of use of PFOI from its generation as an unintended side chain fraction (by-product) of C_6 fluorotelomer production to its reprocessing into TFE. They also question the status of 1-H-PFO as a PFOA-related compound (see section 2 on chemical identity) (FluoroCouncil, 2018a).

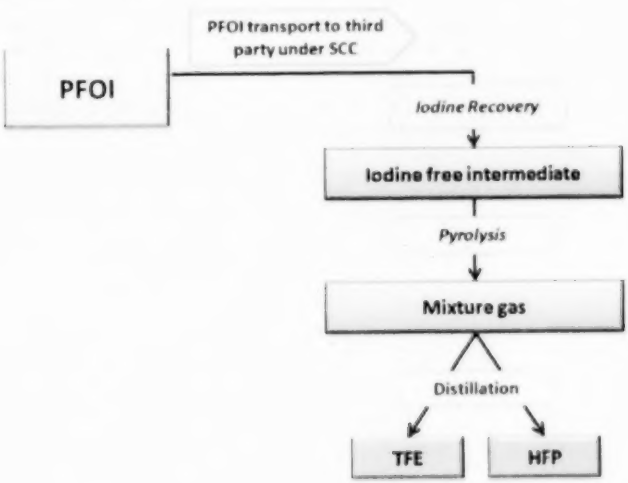
99. Brown et al (2008) completed studies suggesting that PFOI is a PFOA-related compound (amongst 120 substances) predicted to become an Arctic contaminant based on modelling studies. Brown et al (2008) go on to claim that PFOI matches the structural profile of known Arctic contaminants. In vivo studies in male medaka fish show that PFOI upregulates estrogenic genes in a dose-dependent manner indicating that it is an endocrine disruptor (Wang et al. 2011). Wang et al. (2015) showed that in human adrenocortical cells in vitro, PFOI upregulates 10 steroidogenic genes at uM levels of PFOI. GHS hazard statements for PFOI note that it "may cause long lasting harmful effects to aquatic life" and EU precautionary statement codes include P273 (avoid release to the environment).

100. Archroma (a member of the FluoroCouncil), produces C_6 fluorotelomers at one single site, located in Germany. During the C_6 telomerisation, PFOI, is generated as an unintended side fraction of C_8/ long-chain fluorotelomers, the residual fraction includes some longer-chain substances such as $C_{10}F_{21}$-I and possibly $C_{12}F_{25}$-I and other non-fluorinated substances. The composition of the residual fraction is projected to shift further from C_{12} and C_{10} towards C_8 as of 2020 as a result of the reduction effort. This fraction that also consists of $C_{10}F_{21}$-I and possibly $C_{12}F_{25}$-I is sent in closed barrels to a facility in the Republic of Korea where the company claims that iodine recovery and reprocessing to TFE and HFP take place under closed system conditions.

101. In the EU, PFOI is registered as a transported isolated intermediate under REACH[28] for the purpose of its off-site reprocessing and is exempted from the REACH restriction on PFOA (FluoroCouncil, 2018a). According to the FluoroCouncil, PFOI cannot be directly reprocessed via pyrolysis to obtain the desired products TFE and HFP due to iodine contamination which prevents use in downstream polymerisation reactions (FluoroCouncil, 2018a).

102. The FluoroCouncil did not report the current volume of the PFOI fraction to be covered by their proposed exemption, but stated that an R&D project is ongoing with the aim to further reduce this fraction (by a factor 3 to 6). By 2020, Archroma estimates that the volume of PFOI generated as unintended side fraction (by-product) in the production of C_6 fluorotelomers at their manufacturing sites will range between 50 and 100 tonnes per year (FluoroCouncil, 2018a).

103. According to the submission of the FluoroCouncil, reprocessing of PFOI to TFE and HFP takes place via iodine recovery and subsequent pyrolysis (FluoroCouncil, 2018a). TFE and HFP are both non-POP substances. They are used by the facility in the Republic of Korea as raw materials for the production of fluoropolymers and C_6 fluorotelomers. No significant additional releases of PFOI are expected from this process compared to PFOI incineration, particularly as transport would be required in the absence of on-site iodine recovery and given possible emissions from incineration. In the event that the exemption request is not granted, Archroma argued that PFOI could only be stock-piled. As stockpiling is not a viable option, a closure of the production site may have to be envisaged (FluoroCouncil, 2018a).



[28] EU regulation EC 1906/2006 on the Registration, Evaluation, Authorisation and restriction of Chemicals

Figure 4.1 PFOI closed-system reprocessing (FluoroCouncil, 2018a)

104. According to the FluoroCouncil, developing a technology to conduct the on-site iodine extraction by their member would take several years after the entry into effect of the Convention's provisions on PFOA and lead to the production of 1-H-PFO that currently falls under the definition of a PFOA-related compound. substance. The FluoroCouncil argues that degradation of 1-H-PFO to PFOA has never been observed. Provided 1-H-PFO would not be identified as a PFOA-related compound, the transformation of PFOI to 1-H-PFO under a closed system may become eligible to the general exemption provided for in Annex A, Part I, note (iii) or Annex B, Part I, note (iii) for the use of on-site intermediates under closed system in the production of non-POP substances (FluoroCouncil, 2018a). The viability of on-site iodine extraction will depend on the status of the substance, 1-H-PFO. 1-H-PFO. not PFOI, would then need to be transported for reprocessing. Additional information on the status of 1-H-PFO as a PFOA-related compound can be found in the section on the chemical identity (see section 2 on chemical identity).

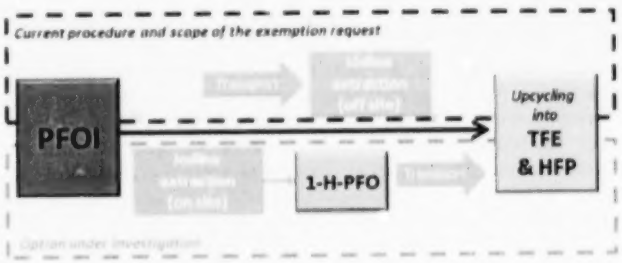


Figure 4.2 Current off-site reprocessing procedure (red dotted line) and on-site processing option (green dotted line) (FluoroCouncil, 2018a)

105. The FluoroCouncil's submission (FluoroCouncil, 2018a) explains the intention of one of their members, Archroma, to transport PFOI as an intermediate for reprocessing at another site at least for a transitional period. The member of the FluoroCouncil submitted information regarding risk management measures to avoid releases. Archroma claims that all steps of the process covered by the exemption request apply the best available techniques and are conducted in closed systems with (1) no contact with water and (2) incineration of off-gases. The only exception relates to the loading/unloading of containers used for the transport of the PFOI fraction, where they claim that strictly controlled conditions are in place (FluoroCouncil, 2018b). Independent verification of these processes was not provided.

106. Archroma indicated that the production personnel are supervised and trained, that all procedures are well documented and most of them are controlled by a process control system. Maintenance operations, (typically unclogging), are conducted with products which are incinerated after use. The C_6 production from which the PFOI fraction results, takes place in a closed system, with all production units being linked by closed pipes. Between the units there are vessels buffering the products. In 2016, Archroma made significant investments which have terminated any contact with water during production, thereby preventing any presence of fluorinated chemistry in waste water (FluoroCouncil, 2018b). They report that the only possible emissions are in the off-gases which are incinerated. The loading and unloading steps for transport in containers take place with local ventilation. Archroma claims that the PFOI fraction is in a liquid form with a very low volatility which further reduces the risk of emissions. The air flow is then filtered by activated carbon adsorption. Filters are incinerated. The workers conducting the operation wear a protective gear. Archroma claims that the transport of the entire unintentional side fraction takes place in dedicated containers and with an experienced specialised shipment company for chemicals. The transformation of PFOI into TFE and HFP including intermediary steps of iodine extraction, pyrolysis and distillation, take place under closed system and in inert gas conditions and that the process is water free. Archroma claims that the only possible emissions are in the residual off-gases which are incinerated (2018). Independent verification of these processes was not provided.

107. A summary of Archroma's risk-management measures in place are displayed below:

Process step	RMM-general	RMM-specific
C_6 production with PFOI fraction	Closed system	No contact with water, off gases incinerated
Loading	SCC	Protective gear, local ventilation, off-gases filtered by activated carbon adsorption, filters incinerated
Transport	Closed containers	Dedicated closed containers, ship equipped to transport hazardous chemicals
Unloading	SCC	Protective gear, local ventilation, off-gases filtered by activated carbon adsorption, filters incinerated
Iodine recovery	Closed system	Inert gas conditions, no contact with water, off-gases incinerated
Pyrolysis	Closed system	Inert gas conditions, no contact with water, off-gases incinerated
Distillation	Closed system	Inert gas conditions, no contact with water, residual gases incinerated

Figure 4.3 Risk-management measures for the handling of the PFOI fraction (Flurocouncil, 2018b)

108. IPEN and ACAT state that the proposed transport exemption would undermine the integrity of the Stockholm Convention in that (they argue) the fluorochemical industry proposed the exemption to enable production of unspecified C_6 fluorotelomers, but these substances have not been evaluated (or even named) to determine if they meet the POPs criteria in Annex D, making it impossible to take the POPs criteria into account as required for closed-system, site-limited intermediates. The data that do exist for commonly manufactured C_6 fluorotelomers indicates that these substances have properties that raise concerns for POPs properties (IPEN and ACAT, 2018a). As an example, IPEN and ACAT provided information from peer-reviewed publications on the properties of 6:2 fluorotelomer alcohol (6:2 FTOH) (IPEN and ACAT, 2018a). In addition, China raised concerns about an increased use of 6:2 PFAS that can lead to an increased concentration of 6:2 FTCA in the environment (China, 2018).

109. In conclusion, IPEN and ACAT (2018) suggest that the Committee should not recommend an exemption for non-site-limited isolated intermediates. The proposed exemption would, according to IPEN and ACAT, also open the door to waste dumping in developing and transition countries under the guise of "reprocessing". IPEN and ACAT argue that this exemption could result in significant further releases of PFOA (IPEN and ACAT, 2018a). Archroma argues that the transport would be subject to the strict rules of Article 3 of the Convention.

4.3.2 Information on alternatives

110. The FluoroCouncil does not mention alternative substances; however, they mention the possibility of on-site treatment of PFOI. This process will reportedly not be available in due time and would lead to the generation of 1-H-PFO, which currently falls under the definition of a PFOA-related compound. The FluoroCouncil argues that 1-H-PFO should not be considered a PFOA-related compound.

4.3.3 Information on impacts on society

111. The FluoroCouncil argues that the need for on-site storage if an exemption is not granted might lead to closure of the production site of their member company. A closure would lead to direct job losses and impact suppliers and downstream users. A treatment of the PFOI fraction in an incineration facility without iodine extraction is not possible as the iodine content causes rapid corrosion of installations at elevated temperatures (FluoroCouncil, 2018b). When considering impacts on society, potential negative e.g. effects in case of a (accidental) release of PFOI have to be taken into account.

4.3.4 Synthesis of information

112. At sites of Archroma (a member of the FluoroCouncil) PFOI is generated as an unintended side fraction (by-product) in the production of C_6 fluorotelomers. According to the FluoroCouncil, their member can currently not process PFOI on-site to TFE and HFP. Therefore, they are requesting an exemption for transporting PFOI as an isolated intermediate to another site for reprocessing to TFE and HFP. Brown et al (2008) completed modelling studies for 120 substances, which suggested that PFOI is a PFOA-related compound with potential to become an Arctic contaminant. Furthermore, the same study indicates that PFOI disrupts the endocrine system, without possibility that it may cause long lasting harmful effects to aquatic life.

113. According to Archroma (2018), developing a technology to conduct the on-site iodine extraction would take several years after the entry into effect of the Convention's provisions on PFOA and would lead to the production of 1-H-PFO which currently falls under the definition of a PFOA-related compound. If on-site iodine extraction were in

place. 1-H-PFO would be transported for reprocessing. If *1-H-PFO would not be considered a PFOA-related compound*, the company might invest in the on-site iodine extraction and then a transitional exemption would be needed for transporting PFOI as an isolated intermediate to another site for reprocessing to TFE and HFP until on-site iodine extraction is possible. In summary, Archroma's proposal requires both an exemption for PFOI transport as an intermediate and the reclassifying of 1-H-PFO as not being a PFOA-related compound. However, present information indicates that 1-H-PFO should be considered a PFOA-related compound (see paragraph 48 above). This topic is currently under discussion at the PBT expert group by the European Chemicals Agency and a conclusion might be available for the 14th POPRC meeting.

4.3.5 Conclusion

114. Based on the evaluation of available information a specific time limited exemption could be considered for the use of PFOI (perfluorooctane iodide) as isolated intermediate in order to enable reprocessing to TFE (tetrafluoroethylene) and HFP (hexafluoropropylene) in another site than the production site. Based on the information provided, the Committee has to decide whether an exemption should be given.

4.4 (c) Medical devices other than implantable devices

4.4.1 Introduction

115. The RME for PFOA highlighted a potential need for more information about a possible exemption for medical devices. The request for information specifically requested information on specific applications/uses and timelines foreseen as needed for potential related exemptions.

116. Relevant information was submitted by Canada (2018), IPEN and ACAT (2018) and MedTech Europe industry association (2018). Information related to medical devices including implantable medical devices was also provided by Healthcare Without Harm (HCWH, 2018)

117. MedTech Europe (2018) provided details in their submission stating that PFOA and PFOA-related compounds are used within medical settings as both non-polymeric substances and side-chain fluorinated polymers[29] (including PTFE). A report by ECHA (2015a) as part of the European restriction estimated global usage of PFOA within medical devices as <5kg p/a (extrapolated from an EU estimate of <1kg p/a and assumed 20% global market share).

118. Within the EU restriction (EU 20171000 amending EC 1907/2006), a time limited exemption (until 4 July 2032) is given for medical devices other than for certain implantable medical devices within the scope of Directive 93/42/EEC (EU Directive concerning medical devices). For the production of implantable medical devices, an exemption without time limitation is given in the EU. Norway has an exemption in place for medical devices (with no time limit). The import, use, sale and offer for sale of medical devices containing PFOA, its salts or PFOA-related compounds are not restricted in Canada. According to the information submitted by IPEN and ACAT (2018), in line with the provisions of the Convention clarity is needed over the specific use being exempted in order to allow ratified parties to easily enforce it. Limited data on specific uses within medical devices has been provided.

119. The RME for PFOA noted that an exemption (with or without time limit) could be considered for use of medical devices. However, a conclusion was not reached at POPRC-13 and the Committee invited Parties and observers to submit further information on specific applications/uses and timelines foreseen as needed for potential related exemptions.

4.4.2 Efficacy and efficiency of possible control measures

Identification of uses of PFOA and PFOA-related compounds in medical devices

120. MedTech (2018) and Euromed (2015) commented that medical device manufacturers encompass up to 11,000 suppliers, with supply chains up to five to seven tiers globally. They suggest that the global supply chain makes collection of information on specific applications difficult. MedTech (2018) further commented that the diverse set of applications and complexity of supply chains makes development of detailed lists of uses extremely challenging. However, MedTech (2018) noted that based on a survey of their members the presence of PFOA and PFOA-related compounds within medical devices will be present as a by-product of PTFE manufacture, where PFOA is used as an emulsifier. The use of PTFE within medical devices is selected based on its chemical resistance, heat resistance, lubrication and biocompatibility. However, it is also important to recognise that alternatives to the use of PFOA

[29] Polymeric Fluorotelomer-based Products are also known as "side-chain fluorinated polymers." These products consist of hydrocarbon backbones with polyfluoroalkyl side chains that stick out like teeth on a comb. These polymers are used to treat textiles, carpets, nonwovens and paper to provide water, soil, oil and stain resistance. https://fluorocouncil.com/fluorotechnology/terminology/

within PTFE, and PFOA-free PTFE products have been developed (discussed further in section 4.4.3 on information on alternatives) and have passed regulatory tests for commercialisation in some geographies.

121. The 2010/15 PFOA stewardship program (which is chaired by the US EPA) which includes eight major manufacturers of PFOA globally, has seen the manufacture of PFOA cease in the EU and decrease dramatically in the US and Japan.[30] However, MedTech (2018) also commented that the main component production is outside of Europe and may use PFOA (produced in China and India) as a raw material input for the production of the applied polymers (Euromed, 2015). Wang et al. (2014) further commented that new production had begun post-2006 in Asia (particularly India and China) primarily driven by the demand for production of fluoropolymers including PTFE. The paper by Wang et al. (2014) estimates production of PFOA and PFOA-related products in China as 50–80 tonnes per annum in 2009, but no disaggregation is provided for uses specifically in medical devices.

122. MedTech (2018) stated that when PFOA is used in PTFE production in generic components, trace quantities can end up in medical equipment such as:

(a) Cable and wiring;

(b) Electronics (insulators, solder sleeves, vapour phase soldering media);

(c) Photographic applications (see section 4.6); and

(d) Medical articles (non-woven medical garments; stain- and water-repellents for surgical drapes and gowns (see section 4.2); surgical patches; and vascular catheters.

123. The above-mentioned components result in applications within a wide range of medical devices including sensors, cardiovascular devices, vascular catheters, protection tubing, implants and orthopaedic devices.

124. A report by ECHA for the European restriction (ECHA, 2015a) comments that the total usage of PTFE and quantities of PFOA or PFOA-related compounds in medical devices are unknown. However, based on the survey conducted with industry, ECHA (2015a) estimates that total quantities of PFOA in medical devices in use across Europe would not exceed 1kg. ECHA (2015a) estimates that the use within the EU makes up 20% of total global demand for PTFE, and therefore by extrapolation total quantities of PFOA in medical devices globally may not exceed 5 kg, based on the assumption that the use of PFOA would be similar in other non-EU geographies.

Timescales foreseen for potential exemptions

125. MedTech Europe (2018) noted that the substitution of substances within the medical sector is likely to differ from substitution in other sectors. This is because of the scrutiny and stringent regulatory requirements for medical equipment. MedTech Europe (2018) go on to state that a change in materials could be perceived as affecting the reliability of the device and would thus trigger the need for evaluation as if the device were a new piece of equipment, including the potential need for clinical trials which would delay the transition. MedTech Europe (2018) state that products that have already entered the supply chain would have a shelf-life of 3 to 5 years, mainly relating to product sterility and therefore an exemption would be needed for a similar period of time. It is not clear whether this relates only to implantable medical devices or to all medical devices.

126. The European restriction (EU 2017/1000) allows an exemption for all medical devices (excluding implantable medical devices) of 15 years and a non-time limited exemption for implantable medical devices. This is expected to expire on 7 July 2032. ECHA considered comment (within ECHA, 2015a) that the reason for the length of the exemption relates to the stringent regulatory requirements for medical equipment which can delay the substitution with alternatives and that a shorter exemption may mean certain critical applications would become unavailable to the healthcare sector.

4.4.3 Information on alternatives

127. Canada (2018) stated as part of the invitation for submissions that the main use of PFOA within medical devices is as a process aid in the emulsion polymerisation of PTFE; however, Canada states that Zero PFOA PTFE products are now available on the market. IPEN and ACAT (2018) also comment that PFOA-free PTFE products have been commercialised and are available on the market within the USA.

128. The RME provided an overview of the main PFOA-free PTFE goods available on the market. In absence of further new information and for ease of reading this information is provided from the RME in the following paragraph.

[30] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfass#tab-3

129. *Three PFOA-alternatives with ether moieties (GenX, ADONA and EEA-NH_4) that are generally shorter and or less fluorinated were assessed in the EU restriction process (ECHA, 2015b, section C3). C_3 Dimer salt,[31] ADONA and EEA-NH_4 are applied as alternatives for the use of PFOA as polymerization processing agent where it is applied as emulsifying agent enabling reactants from the aqueous phase and reactants from the hydrophobic phase to get into contact in an emulsion and react with each other (ECHA, 2015b). According to ECHA most of the stakeholders stated that there are no technical differences between fluoropolymers produced with the alternatives and fluoropolymers produced with PFOA (or stakeholders do not know whether there are any differences) (ECHA, 2015b). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from none to 20% increase when applying the alternatives (ECHA, 2015b). The increase is a result of higher costs of the alternatives as well as higher amounts of the alternatives needed to manufacture one unit of fluoropolymer. Some downstream users mentioned that no cost effects occurred after substitution from PFOA to alternatives.*

130. Further information around the persistent, bioaccumulative and toxic (PBT) properties of potential alternatives is detailed within the RME.

4.4.4 Information on impacts on society

131. MedTech Europe (2018) commented that health risks of medical devices are adequately assessed during regulatory procedures before the placing on the market. The European medical device industry commented that they fully supported a phase out of PFOA but requested a limited time exemption in order to avoid market disruption and allow for a substitution that is properly enforceable. Regarding waste implications, the amount of PFOA in question is considered to be small and it can be expected that most medical devices would be disposed of according to the stringent waste disposal requirements applicable to hospitals. However, the stringency of medical waste disposal practices will vary.

4.4.5 Other considerations

132. None.

4.4.6 Syntheses of information

133. MedTech Europe (2018) noted that, based on a survey of its members, PFOA will mainly be present in medical devices as a by-product of PTFE manufacture. However, it is also important to recognise that alternatives to the use of PFOA within PTFE, and PFOA-free PTFE products have been developed (Nesbitt, 2017). MedTech Europe (2018) and Euromed (2015) both highlighted the difficulty in producing detailed lists of specific applications within healthcare due to the diverse ways in which PTFE is used. However, in line with the provisions of the Convention, a use of PFOA should be specifically identified to enable consideration of a specific exemption. Generic uses of PTFE in medical devices include cables and wiring, electronics (such as insulators, solder sleeves, and vapour phase soldering media), photographic applications, medical articles (such as non-woven garments, stain and water repellents for surgical drapes and gowns, and vascular catheters. ECHA (2015) made estimates to quantify PFOA and PFOA-related compounds in medical devices, estimating that these are at or below 1kg for Europe and below 5kg globally.

134. ECHA (2015a) noted that substitution to alternative substances may be more challenging in the healthcare sector due to the stringent regulations applied, which can include the need for clinical trials. This was a point also made by MedTech (2018) and Euromed (2015). The European restriction includes a 15-year exemption for medical devices due to expire on 4 July 2032. ECHA commented (ECHA, 2015a) that such an exemption was needed to aid transition and prevent critical applications becoming unavailable.

135. The RME states that alternatives have been developed and commercialised, including Zero PFOA PTFE.

136. The RME indicates that three key alternative products exist with ether moieties (GenX, ADONA and EEA-NH_4) that are generally shorter and/or less fluorinated than what was assessed in the EU restriction process (ECHA, 2015a, section C3). C_3 Dimer salt, ADONA and EEA-NH_4 are applied as alternatives for the use of PFOA as a polymerisation processing agent where it is applied as an emulsifying agent enabling reactants from the aqueous phase and reactants from the hydrophobic phase to get into contact in an emulsion and react with each other (ECHA, 2015b). According to ECHA most of the stakeholders stated that there are no technical differences between fluoropolymers produced with the alternatives and fluoropolymers produced with PFOA (or stakeholders cannot recognise any differences) (ECHA, 2015b). Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from zero to a 20% increase when applying the alternatives (ECHA, 2015b). The increase is a result of higher prices of the alternatives as well as higher quantities of the alternatives needed to manufacture one unit of fluoropolymer. However, some downstream users mentioned that no cost effects occurred after substitution from PFOA to alternatives (ECHA, 2015b).

[31] IUPAC name: Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate; CAS No: 62037-80-3.

137. The main societal effects related to the continued use of PFOA-based PTFE or a restriction on PFOA-based PTFE for medical devices relates to the availability of devices for use in the healthcare sector (MedTech Europe, 2018). MedTech Europe (2018) and Euromed (2015) both highlight that regulations within the healthcare sector are stringent, and that alteration of substances within devices can mean the need for retesting, including potentially clinical trials. This reportedly delays the transition to alternative products. However, alternatives that do not use or contain PFOA have already passed medical regulations in at least some geographies, and are commercially available.

4.4.7 Conclusion

138. Based on the information compiled and discussed within the RME and further elaborated upon within the current document, alternative medical devices made without PFOA are available on the market and in use. However, the evidence reviewed suggests that phase-out is still ongoing for some uses and therefore a time-limited exemption may be needed for medical devices to prevent loss of critical applications. Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in medical devices.

4.5 (d) Implantable medical devices

139. The RME for PFOA highlighted a potential need for more information about a possible exemption for implantable medical devices. The Committee invited Parties and observers to submit further information on the scope of the applications of use, used amounts, extent of transport and risks and other relevant information on socio-economic aspects. Relevant information was submitted by Canada (2018), IPEN and ACAT (2018), Healthcare Without Harm (HCWH, 2018) and MedTech Europe (2018).

140. Within the EU restriction (EU 2017/1000), an exemption without time limit is currently given for the production of certain implantable devices.

4.5.1 Efficacy and efficiency of possible control measures

141. Information submitted to ECHA (2015a) indicates that amounts of PFOA and PFOA-related compounds related to this use are estimated to be extremely low. In implantable devices, one manufacturer previously estimated that the total amount of PFOA present in all devices put on the market in the EU during the period 2018–2025 without the restriction would amount to 20 g (it is however unclear if this amount includes only PFOA or also PFOA-related compounds). This was extrapolated to 100g total worldwide by the industry assuming that the EU occupies 20% of the market assuming similar usage in other non-EU geographies (MedTech Europe, 2018). The concentration of PFOA in PTFE is stated to range from 0.001 to 0.5% for emulsion route material (ECHA, 2015b), with a comment from ECHA that confidential information indicated that the working concentrations for implantable medical devices would be at the lowest concentration range (ECHA, 2018).

142. MedTech Europe (2018) commented that a specific exemption for implantable cardiovascular devices until 2030 would be sufficient to allow transition to alternatives without impacting the European healthcare sector. ECHA (2015a) commented that a derogation for implantable medical devices in the EU was needed given the very low amounts of PFOA and PFOA-related compounds involved and high costs reported for immediate transition.

143. Further information and data on quantities used, extent of transport and risks, and use of PFOA in implantable medical devices was not provided in response to the request for information.

4.5.2 Information on alternatives

144. Implantable medical devices, such as cardiovascular devices catheters and guidewires, can contain PTFE made from PFOA. However, PTFE can be made without PFOA (HCWH, 2018) and alternatives are reportedly now commercially available, approved by US Food and Drug Administration (FDA), and are a feasible and effective alternative to the use of PFOA. (IPEN and ACAT, 2018). A number of commercialised PFOA-free PTFE medical devices are now available.[32] [33] [34] [35]

[32] http://www.surfacesolutionsgroup.com/site/files/785/69121/273265/759549/no-pfoa-ptfe-coatings-guidewires-brochure.pdf.

[33] https://meritoem.com/composite-reinforced-coatings-the-future-of-medical-device-coatings/.

[34] http://store.tegramedical.com/zero-pfoa-green-ptfe-wire/.

[35] https://wytech.com/wire-components/.

145. The main issue for alternatives is the resistance to saline solutions, but also some low friction technical issues may still exist (Nesbitt, 2017). In 2016, a US FDA recall on PFOA-free PTFE products used for medical implants occurred in the US[36] due to problems with flaking and delamination in the body (Gupta et al. 2016). If these flakes pass to the bloodstream they have the potential to cause serious health effects such as heart attack, stroke and blood clots (Nesbitt, 2017; Gupta et al. 2016). The second generation of PFOA-free PTFE products have resolved the bonding issue by changing manufacturing processes related to surface preparation, coating viscosity and solids content, humidity, airborne particulates, spray pressure, temperature, electrostatic voltage, spray pattern, coating line humidity and line speed, among others (Nesbitt, 2017). Nesbitt (2017) also notes that processes following these altered practices have resulted in zero Class 1 FDA recalls.

146. Fluoropolymer manufacturers stated during the EU public consultation that the production costs varied from none to 20% increase when applying the alternatives (ECHA, 2015b). This increase arises from the higher costs and/or the higher amounts of alternatives that will be used, however during a previous request (in 2015) for information, EU Industry stated that there is no change in the quality of the PTFE manufactured with the alternatives (ECHA, 2015b).

147. In the EU public consultation, industry stakeholders indicated that substitution is ongoing but is a lengthy process given the complexity of the supply chains and the certification processes (ECHA, 2015a). In the specific case of implantable medical devices, one manufacturer requested a transition period of 15 years (ECHA, 2015c). This request was supported by a socio-economic analysis comparing the costs of not using the devices with the avoided emissions. ECHA found that, even if all costs were not clearly justified and might include some overestimation, this socio-economic analysis demonstrated that a shorter transition period than requested would not be cost-effective (ECHA, 2015a).

148. Further information on the alternatives to PTFE can be found in section 4.4.3 on medical devices.

4.5.3 Information on impacts on society

149. Implantable medical devices range from synthetic vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair, to sutures for use in vascular, cardiac, and general surgery procedures. These devices allow for example for minimally invasive insertion, and the innovative materials are biocompatible, homogenous and versatile. MedTech Europe (2018) noted that they had concerns regarding patient safety if critical implantable medical devices became unavailable due to lack of transition time to PFOA free alternatives (MedTech Europe, 2018). The RME and addendum notes that examples have been provided of cases where PFOA-free alternatives have been developed and are already in use for some geographies. However, it is unclear whether this is the case for all global geographies.

4.5.4 Syntheses of information

150. Quantities of PFOA and PFOA-related compounds used in implantable medical devices (largely for production of PTFE) are small (estimated to be 20g in the EU and 100g worldwide) and concentrations are low in the final product (PFOA in PTFE is stated to range from 0.001 to 0.5%; while personal communication with ECHA noted that based on engagement with industry and confidential data concentrations in implantable medical devices were lower than general PTFE). In addition, the development of alternatives for substitution is complex due to stringent regulatory requirements for material changes to medical devices but alternative PTFE coating methods are available and already in use. The past performance of PFOA-free PTFE alternatives has been subject to concern by the US-FDA (due to problems with flaking and delamination in the body) but improved manufacturing methods have resulted in zero Class 1 recalls. The RME indicates that the use of alternatives also induces a low to moderate increase in production costs (0–20%) and is paired with a net benefit to society in terms of human health impacts, through the reduced use of PFOA in human implants.

4.5.5 Conclusion

151. Cost competitive alternatives, such as PFOA free PTFE products have already undergone clinical testing, been approved and have been implemented for use in medical implants including cardiovascular devices in some geographic areas, such as North America (Nesbitt, 2017). However, it is unclear whether this transition has been made in all global geographies. While industry representatives (MedTech, 2017) have indicated significant progress has been made towards the phase-out of PFOA within implantable medical devices, industry indicates that supply chains are complex and that articles are subject to stringent regulatory testing requirements. Therefore, the Committee could

[36] Nesbitt, 2017 comments that in October 2016 Medtronic a major supplier of guidewires used in medical implants had to recall 84,000 units after problems. Nesbitt notes that Medtronic was not the only supplier that needed to issue a recall as part of the US FDA recall.

consider the need for a time-limited exemption to aid the transition to safer alternatives. It could also consider whether such exemption is needed only for cardiovascular implantable medical devices.

4.6 (e) Photo-imaging sector

4.6.1 Introduction

152. The RME recommends to the COP considering an exemption for five years (from the date of entry into force) for photographic coatings applied to films. However, the RME also highlighted the need for more information about a small number of relevant uses of PFOA in the photo-imaging sector. Within the EU an exemption from the REACH restriction is in place for photographic coatings applied to films, papers or printing plates without time limitation (EU 2017/1000). Specific exemptions applied in Norway and Canada until 2016 but are now ended (See appendix I). The Norwegian risk management approach only applies to consumer products and the Canadian approach does not apply to manufactured items.

153. At POPRC-13, representatives of the European photographic imaging industry provided information for the RME that suggested time-limited exemptions for photographic coatings applied to paper and for use in printing plates are no longer needed. Non-perfluorinated alternatives have successfully replaced some uses in the imaging and printing industry and the move to digital imaging will replace the need for PFOA. PFOA use in photo-imaging has been reduced by more than 95% worldwide since 2000 (I&P Europe). However, it was also noted that for developing countries, such information was lacking.

154. A conclusion on photographic coatings applied to paper and in printing plates was not reached at POPRC-13 and the Committee invited Parties and observers to provide information on photo imaging, specifically in relation to photographic coatings applied to paper and in printing plates and in developing countries.

155. Relevant information was submitted by the Netherlands (2018a), IPEN and ACAT (2018) and Healthcare Without Harm (HCWH, 2018).

4.6.2 Efficacy and efficiency of possible control measures

156. This section provides information on PFOA in photographic coatings applied to film, to paper and printing plates and additional evidence on use in developing countries.

Use in photographic coatings applied to film, paper and printing plates

157. Industry expects that the use of PFOA and PFOA-related compounds is likely to cease within 10 years (from 2014) when stocks are exhausted and remaining applications will have been replaced by digital techniques (ECHA, 2014a).

158. In these uses, PFOA and PFOA-related compounds are bound to a coating matrix, which is covered by other layers of the photographic material. The concentration of PFOA in articles is stated to be in the range of 0.1–0.8 µg/cm² (ECHA, 2014a). The use of PFOA in photographic applications is strongly decreasing owing to the transition to digital techniques. According to European industry, < 0.1 t of PFOA and <0.1 t of PFOA-related compounds were used in the EU in 2013 in photographic applications (ECHA, 2014a). European industry assumes environmental releases and exposure potential to be low during manufacturing (I&P Europe, 2015).

159. The submission by the Netherlands (2018a) provided information that PFOA has been replaced in most applications within the EU. Analogue applications have largely been replaced by digital, but precise percentages are not available. Forecast numbers previously indicated a further reduction of PFOA and PFOA-related compounds use in Europe to about 0.12 t/yr in 2015 and 0.088 t/yr in 2016 (ECHA, 2015b), amounting to a further reduction of the use of PFOAs in the whole photographic industry to respectively 96.4% and 97.5% since 2000 (I&P Europe, 2015).

Use in developing countries

160. IPEN and ACAT (2018) provided multiple examples (from countries such as Gabon, Kazakhstan, Kenya, South Africa, Latin American region, and remote Arctic communities) where digital imaging has been adopted in developing countries in favour of hardcopy printing. As another example, the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO) note that there has been a marked transition towards digital technologies in developing and transition countries. In particular the IAEA and WHO note that the rapid adoption of digital technology in healthcare results from "efficiencies inherent in digital capture, storage and display and the

competitive cost structures of such systems when compared to alternatives involving film[37]" (IAEA & WHO, 2015).".[38]

161. Further information on use of PFOA or PFOA-related compounds in developing countries in other industry sectors (other than healthcare) was not received in response to the call for information.

Control measures

162. It is indicated by I&P Europe member companies that most photo-imaging products do not contain PFOA or PFOA-related compounds (I&P Europe, 2015). The RME provides text which states that for waste materials, which are associated with the manufacture of a small number of films containing PFOA or PFOA-related compounds, are typically disposed of by high temperature incineration and excess coating formulations may be sent for silver recovery. Thereby, the waste is incinerated at high temperatures (I&P Europe, 2016). This represents the situation in Europe (IPEN Comments on 1st draft RME). Information for other geographies has not been identified.

163. Due to lack of data, substitution costs in response to a restriction for photographic applications cannot be estimated and no further up to date information has been received in response to the call for information. This may be due to the extensive transition to digital technologies that has already occurred, however more information on cost of substitution would be useful.

164. Monitoring data linked directly to the photographic sector is very limited and no additional data has been submitted in response to the recent call for information.

4.6.3 Information on alternatives

165. *According to I&P Europe, since 2000, European industry has reformulated/discontinued a large number of products, resulting in a world-wide reduction in the use of PFOA-related compounds of more than 95%. Although replacements do not currently exist for the remaining few applications, further reduction in use of PFOA-related compounds is anticipated as the transition continues towards digital imaging. I&P Europe believes that additional control measures for ongoing uses are not necessary (I&P Europe, 2016). A study by van der Putte et al. (2010) suggests that no alternative currently exists and the significant investment required in R&D to switch to an alternative means it is likely that manufacture and use of PFOA or PFOA-related compounds in the photo-imaging sector could cease (ECHA, 2014a). The largest barriers to development reportedly remain technical and cost of R&D. They suggest that substitution of PFOA typically amounts to 500–1,000,000 Euro for a single photographic material. The economic cost associated with substitution of PFOA in the few remaining critical photographic uses has in most cases become prohibitive, the small remaining critical uses being niche products in markets that I&P Europe members anticipate to further decline (I&P Europe, 2015).* For these reasons, the industry has shifted to digital technologies.

166. The Netherlands (2018a) provided information stating that they have created a replacement programme for PFOA. For substitution, the first option is to look at non-fluorine substances if applicable. The PFOA products concerned (Amfluk and Kapri) were replaced where possible by a combination of non-fluorinated products and/or degradable fluorinated compounds where no PFOA arises following degradation.

4.6.4 Information on impacts on society

167. According to representatives of the European photo industry, control measures implemented by the photo-imaging industry, including reformulation and product discontinuance, have reduced the use of PFOA-related compounds worldwide by more than 95%. The emissions from the small number of ongoing uses by the photo-imaging industry have been assessed by a number of competent authorities in the EU, including ECHA, and determined not to pose a relevant risk to the environment or human health (I&P Europe, 2016).

4.6.5 Syntheses of information

168. According to I&P Europe, since 2000, European industry has reformulated/discontinued a large number of products, resulting in a worldwide reduction in the use of PFOA-related compounds of more than 95%. Analogue printing is being phased out and replaced rapidly by digital, including in developing and transition countries. IAEA and WHO note that the rapid adoption of digital technology results from "efficiencies inherent in digital capture, storage and display and the competitive cost structures of such systems when compared to alternatives involving

[37] Note, that the use of PFOA for film is already covered by an exemption stated in the RME. The addendum covers the use for printing on paper and plates. The example is however included to evidence the transition towards digital technologies.

[38] Note, that the use of PFOA for film is already covered by an exemption stated in the RME. The current document covers the use for printing on paper and plates. The example is however included to evidence the transition towards digital technologies.

film." No chemical alternative currently exists largely due to the economic cost and time investment necessary for development in what is a small commercial use sector and this is likely to result in phase out of products before an alternative can be found.

4.6.6 Conclusion

169. Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transitional countries, and the further reduction in use of PFOA in this sector, no exemptions for photographic coatings applied to paper and printing plates should be considered necessary.

4.7 (f) Automotive industry

4.7.1 Introduction

170. The RME highlighted the need for more information about the uses in automotive service and replacement parts. According to the RME, an exemption for automotive service and replacement parts could be considered under the Stockholm Convention. However, specification of relevant automotive service and replacement parts as well as sound justification for any exemption is required. No related exemptions have been given in the EU and Norway (see the RME) and no exemption is granted in the EU REACH restriction.

171. The Committee invited Parties and observers to submit further information on automotive spare parts and other relevant information. Information was submitted by the Canadian Vehicle Manufacturers' Association (CVMA, 2018), European Automobile Manufacturers Association (ACEA, 2018), Society of Indian Automobile Manufacturers (SIAM, 2018), Canada (2018) and IPEN and ACAT (2018).

4.7.2 Efficacy and efficiency of possible control measures

172. During the development of the RME, *the CVMA requested specific exemptions for automotive service and replacement parts. The request for exemption is also supported by the European (ACEA) and Indian (SIAM) automotive industry. According to the CVMA, the industry has been proactively phasing out PFOA use for some time, however, service and replacement parts might still contain PFOA. CVMA states that these parts represent a small percentage of PFOA use and will decrease naturally over time due to vehicle fleet turn-over. Automotive manufacturers indicated the need to ensure the availability of Original Equipment (OE) and spare parts to satisfy customer demand* (see the RME).

173. In their recent submissions, CVMA requests an exemption for automotive vehicle service and replacement parts as well as current production vehicles given the complexity of the sector and the actions already undertaken by the industry. The request for exemption in new vehicles is related to potential use of PFOA-related compounds that are not listed on the Global Automotive Substance List (GADSL) or listed on GADSL but used below the declaration concentration of 0.1%. It is further stated that an exemption was provided for service and replacement parts when the Convention was deliberating the addition of decaBDE and the same exemption should be applied for PFOA. The issues and challenges would reportedly be similar (CVMA, 2018). IPEN and ACAT (2018) point out that the recommended exemption by POPRC is limited to parts used in legacy vehicles.

174. CVMA further explains that it is challenging to provide meaningful information in support of the required exemption for PFOAs used in the automotive industry. According to CVMA, this is in particular challenging as PFOA is unlike other substances examined under the Stockholm Convention identifiable by a single CAS number. The efforts have been focused so far on a selected number of PFOA-related compounds as information was not available on a broad number of PFOA-related compounds. CVMA doubts that it would be possible, as a manufacturer of a finished product (a vehicle) to collect information from a large, complex, tiered global supply chain without using clear and accurate identifiers for substances. This has also been expressed by ACEA (2018) and SIAM stating that this would require a great amount of time (SIAM, 2018). Further, CVMA points out that auto manufacturers are users and purchasers of a large number of chemicals and products which are supplied locally or imported from around the world for the purpose of assembling vehicles. The information on PFOA and other substances is derived from information disclosed by the supply base through the International Material Data System (IMDS) or provided in Safety Data Sheets, and the level of information disclosed is dependent on thresholds for disclosure limits and the availability of CAS numbers. Without access or availability of information, the industry is not able to confirm the presence of a substance (CVMA, 2018).

175. According to CVMA, the automotive industry has recognised the concerns with certain PFOA-related compounds and has taken proactive efforts to track and reduce those substances in products. Five (5) compounds were added to the GADSL (www.gadsl.org) in 2008, 3 substances in 2016 and another 4 in 2018 (see below). These substances tend to be used at very low levels and probably not all uses have been identified (CVMA, 2018).

Table 4.1 list of PFOA-related compound on GADSL provided by CVMA (2018)

Name	CAS NR	Addition Date to GADSL
Ammonium salt of PFOA	3825-26-1	1-Feb-2008
Potassium salt of PFOA	2395-00-8	1-Feb-2008
Silver salt of PFOA	335-93-3	1-Feb-2008
Sodium salt of PFOA	335-95-5	1-Feb-2008
PFOA – perfluorooctanoic acid	335-67-1	1-Feb-2008
Ethylperfluorooctanoate	3108-24-5	1-Feb-2016
Methylperfluorooctanoate	376-27-2	1-Feb-2016
Pentadecafluorooctyl fluoride	335-66-0	1-Feb-2016
Poly(oxy-1,2-ethanediyl), α-(4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-2-hydroxyundecyl)-ω-[(4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-2-hydroxyundecyl)oxy]-	122402-79-3	Feb-2018
2-Propenoic acid, C16-18-alkyl esters, polymers with 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptadecafluorodecyl acrylate	160336-09-4	Feb-2018
Cyclotetrasiloxane, 2-(4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoroundecyl)-2,4,6,8-tetramethyl-, Si-[3-(oxiranylmethoxy)propyl] derivs	206886-57-9	Feb-2018
Trisiloxane, 3,3'-(3,3,4,4,5,5,6,6,7,7,8,8-dodecafluoro-1,10-decanediyl)bis[3-[(dimethylsilyl)oxy]-1,1,5,5-tetramethyl-, reaction products with 4,4,5,5,6,6,7,7,8,8,9,9,10,10,11,11,11-heptadecafluoro-1-undecene	185701-89-7	Feb-2018

176. Only 12 PFOA salts and precursors are declarable under GADSL and therefore many of the other PFOA salts and precursors could potentially be present in production vehicles without the knowledge of the manufacturers. An initial evaluation of the non-exhaustive list of PFOA-related compounds (i.e. UNEP/POPS/POPRC.13/INF/6/Add.1) shows that 24 individual CAS numbers have been identified by suppliers as potentially being used in the sector. This is twice as many CAS numbers as are currently listed in GADSL which means the presence of PFOA-related compounds is still not known in parts. This also supports that there may be other PFOA used in service and replacement parts which the industry is unware of as the uses have not been declared according to CVMA. Further, it is important to highlight that the 12 PFOA and PFOA-related compounds are included in GADSL if they are used at a concentration above 0.1%. Consequently, all uses may not be known and sufficient lead time is required in the Canadian automotive industry to collect meaningful information. This process typically takes at least one full design cycle of approximately 5 years (CVMA, 2018).

177. Regarding service and replacement parts, CVMA has indicated that most likely service and replacement parts still contain PFOA, its salts and PFOA-related compounds. According to CVMA these parts represent a small percentage of the PFOA use and the amount will decrease naturally over time as the vehicle fleet turns over. Vehicle manufacturers normally ensure the availability of the OE service and replacement parts for a minimum of 15 years to satisfy consumer demand and potentially certification and quality requirements. Typically, parts may be built and stocked at the time of vehicle production or built to the original specifications, including compositions, in short production runs after the new vehicle production ends. The cost of replacing a class of substances in a small number of parts is according to CVMA prohibitive. However, no further information on costs has been disclosed. Further according to CVMA, it should be noted that repair parts need to meet the same performance specifications as the original parts. Based on replacement part availability obligations as noted above, the vehicle manufacturers are working to address the PFOA-related compounds listed from replacement parts by 2036 provided the effective date of the ban is 2021; for PFOAs substances not known, this would take much longer (CVMA, 2018).

178. CVMA further explains that each vehicle manufacturer in general carries over 250,000 active replacement parts, with roughly 20,000 new service parts added annually. The number of parts maintained in inventory and its location (Canada or US) depends on expected consumption and future ability to manufacture. To the extent that customers need replacement parts beyond what is initially stocked, there is a "production-on-demand market" whereby suppliers continue to produce replacement parts using original tools, materials and production processes. (CVMA, 2018).

179. Re-developed replacement parts must function identically to the original part to ensure the vehicle's functionality and safety are not adversely impacted. It could also result in parts being purchased by consumers from jurisdictions where the original type part or an inferior performing variant could be obtained (CVMA, 2018).

180. Regarding the quantity of PFOA in spare parts (manufactured articles in finished vehicles), CVMA is not able to provide this information given the limited information and CAS numbers. Based on the typical function of

PFOA-related compounds which is to repel dirt and water/moisture, it is typically found in areas such as vehicle safety restraint systems and air bag systems, as well as specialised gaskets, seals and weather -strippings, linings in engines, fuels and transmission systems, windshield washer arms, hoses, wirings, o-rings, cables and other areas not yet identified (subject to change). Concentrations tend to be less than 1% in the material and many are at concentrations less than 0.2%. Concentrations reported by two CVMA member companies were 5 times lower than the 0.1% GADSL threshold and less than 0.01%, respectively (information on the spare parts probed and exact PFOA-related compounds was not disclosed). The mass of PFOA in various components as a result of these low concentrations is also very small (CVMA, 2018). No specific information (e.g. quantities of the 12 PFOA-related compounds from the GADSL contained in spare parts) has been provided by CVMA. SIAM reports use of PFOA in vehicles safety restraints an air bag systems, fuel and transmission systems, fuel hoses, wire insulations and bearings (SIAM, 2018).

181. Regarding recycling activities of articles containing PFOA, no information is available (CVMA, 2018).

182. In contrast to the request for exemption information submitted by CVMA, IPEN and ACAT (2018) stipulate that key automotive industry associations have notified company members and suppliers that PFOA will be listed in the Stockholm Convention as well as being regulated in the EU and that "these substances should be substituted."[39] CVMA (2018), however, indicates that they are unaware of key automotive associations notifying their members on a global basis and that this may have occurred on a regional basis rather than in a broader global context. The automotive industry also notes that, "most suppliers producing relevant articles, like waterproofed convertible roofs or PTFE-coated seals, no longer use PFOA or other long-chained perfluorinated chemicals."[39] In the past PFOA has been used to make fluoropolymers used in automotive fuel systems but several companies have alternative emulsifiers so that PFOA has been eliminated in this class of automotive products.[40] IPEN and ACAT (2018) commented that during the year-long process of developing the PFOA RME the industry did not indicate any exemption interest, despite being fully aware of the Committee's process due to their involvement with decaBDE (IPEN and ACAT, 2018). The CVMA (2018) further commented that while efforts had been made to engage with the Committee's process, there have been limitations to providing further information in this case because PFOA and PFOA-related compounds covers many substances and therefore represents a significant challenge for data gathering compared to decaBDE which was based on a single substance. IPEN and ACAT advice that no exemption for PFOA use in the automotive industry should be recommended (IPEN and ACAT, 2018).

4.7.3 Information on alternatives

183. The information from the RME and the new submissions confirm that the phase-out of PFOA, its salts and PFOA-related compounds is ongoing in the automotive industry. Technical and/or economically feasible alternatives for PFOA exist at least in part for the automotive industry. The typical areas of application have been indicated by the automotive industry, however, a complete overview is not available, yet.

184. Information gathered indicates that the key obstacle towards a complete phase-out of PFOA in automotive service and spare parts by the entry does not appear to be the lack of alternatives but rather other obstacles such as costs, because additional costs arise for the certification of PFOA free alternative spare parts. These costs are considered prohibitive by the automotive industry; however, no further information has been provided by the industry related to associated costs.

4.7.4 Information on impacts on society

185. According to the RME, *general concerns of EU industry stakeholders are related to placing on the market and use of spare parts of various types already manufactured (e.g. in aviation, telecommunication, semiconductors, etc.). According to their comments, in the absence of derogation, those spare parts would have to be destroyed, which would represent an economic loss for EU manufacturers* (see the RME). However, this loss will not occur since spare parts containing PFOA, its salts and related compounds manufactured before the entry into force of a listing under the Stockholm Convention would not be covered by the listing (see Annex A, part I, note (ii) and Annex B, part I, note (ii) respectively).

186. CVMA and SIAM state, that vehicle manufacturers normally ensure the availability of the OE for service and replacement parts for a minimum of 15 years. According to CVMA, typically, parts may be built and stocked at the time of vehicle production or built to the original specifications, including compositions, in short production runs after the new vehicle production ends. It should be noted that repair parts need to meet the same performance specifications as the original parts.

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[39] http://www.acea.be/uploads/publications/20160704_INFORMATION_LETTER_TO_SUPPLIERS_ON_PFOA.pdf

[40] http://atozplastics.com/upload/literature/Fluoropolymers-application-automotive-fuel-engine-systems.asp.

187. Re-developed replacement parts must function identically to the original part to ensure the vehicle's functionality and safety are not adversely impacted. The cost of replacing a class of substances in a small number of parts is prohibitive according to industry. It could also result in parts being purchased by consumers from jurisdictions where the original type part or an inferior performing variant could be obtained (CVMA, 2018). According to IPEN and ACAT, testing results can be applied to both new and old vehicles.

188. Prohibiting PFOA use for automotive applications would have a positive impact on human health and the environment by limiting further PFOA releases and exposures and have a positive impact on businesses making alternatives, particularly non-fluorinated alternatives (IPEN and ACAT, 2018).

4.7.5 Syntheses of information

189. The information from the RME and the new submissions confirms that the phase-out of PFOA, its salts and PFOA-related compounds is well-advanced and ongoing in the automotive industries.

190. In their recent submissions, CVMA requests an exemption for automotive vehicle service and replacement parts as well as for current production vehicles. According to the Stockholm Convention Annex A, part I, note (ii) and Annex B, part I, note (ii) respectively, an exemption is not required for service and replacement parts and vehicles manufactured before the date of entry into force of the listing of PFOA, its salts and related compounds. An exemption would therefore only be relevant for service and replacement parts and vehicles manufactured produced after the entry into force of the obligation. However, CVMA further stipulates that even with the mentioned provisions, an alternative timing for the phase-out of automotive service and replacement parts is still needed due to a number of reasons. Among others, the industry cannot assume that a substance is not present given disclosure thresholds and other limitations according to CVMA. Service and replacement parts for current and already produced vehicles are made available for a minimum of 15 years. Furthermore, CVMA highlights that due to the breadth or level of detail regarding all PFOA-related compounds used in the automotive sector comparisons to the data requirements used previously for decaBDE are unfair (CVMA, 2018).

191. According to CVMA, a key obstacle in a complete phase-out of PFOA in automotive service and spare parts by the entry into force of a possible amendment of Annex A appears to be the prohibitive costs. However, no information on possible cost implications has been submitted. In addition, the Canadian automotive industry has concerns regarding practical challenges related to the numerous CAS numbers of affected substances. This has also been expressed by automotive associations ACEA and SIAM.

192. According to CVMA, the level of PFOA usage in the sector is unknown but expected to be low as a result of reported concentrations. However, CVMA have declared 12 PFOA salts and precursors under GADSL. Given this, the industry has some information on 12 substances and at least 1 of the substances listed on GADSL is identified by CVMA as being used in the sector. Another PFOA-related compound, which is not been listed on GADSL has been identified by at least one OEM or a supplier as being used in the industry. No specific information (e.g. quantities of the eight PFOA substances from the GADSL) has been provided by CVMA so far.

193. For these identified PFOA-related compounds and other substances on the non-exhaustive list of substances (UNEP/POPS/POPRC.13/INF/6/Add.1), specific uses in typical service and spare parts as well as quantities should be made available to enable the evaluation of a possible exemption. Until now only a generic list of application areas is provided. This is especially the case if this exemption should take a similar approach as for decaBDE, as requested by CVMA in their recent submission. Based on specific information about relevant spare parts a list of relevant spare parts and categories could be established similar to the approach for decaBDE. The starting point for this could be the parts/categories already specified above, e.g. vehicle safety restraints and air bag systems, gaskets or seals in coatings or lubricants, gaskets, seals and linings in engine, fuel and transmission systems. This information could be supplemented with further information on available alternatives already commercially in use.

194. The Committee requested specification of relevant automotive service and replacement parts as well as sound justification as to why an exemption is required. The Committee invited Parties and observers to submit further information on automotive spare parts and other relevant information available. Limited information was submitted on socio-economic aspects and the availability of alternatives. No conclusive information was submitted so far on the specification of relevant automotive service and replacement parts and on the quantities of relevant substances used in different applications. Further information such as amounts used in different parts is considered necessary to justify a recommendation for an exemption.

4.7.6 Conclusion

195. Based on the review of updated information a time limited exemption could be considered for automotive service and replacement parts and vehicles. However, additional information should be made available by the automotive industry. No conclusive information has been provided on the specification of relevant automotive service and replacement parts (specific parts or categories of parts) and on the quantities of relevant substances used in different applications. Information such as amounts used in different parts is considered necessary to justify a

consideration of a recommendation for an exemption. Further information on time for phase-out, estimation of economic impacts, alternatives in place and retrofitting capacity would be supportive for further discussions at international level.

4.8 (g) Fire-fighting foams

4.8.1 Introduction

196. The RME identified that aqueous film-foaming foams (AFFFs) may contain PFOA or PFOA-related compounds. This raised concerns at POPRC-13 due to the fact that the use of fire-fighting results in the dispersive and potential direct release to the environment.

197. Fluorinated compounds have been used in AFFF as they have proved effective at extinguishing liquid fuel fires. AFFF was reserved specifically for liquid fuel fires. (ECHA, 2014a). In the past industry has favoured the use of C_8 based perfluorinated compounds,[41] including PFOS (which has subsequently been added to the Stockholm Convention as a POP). These materials were largely produced using electrochemical fluorination (ECF), with hydrogen fluoride used as a feedstock alongside organic material (Swedish Chemicals Agency, 2015). Seow (2013) comments that the intentional use of PFOA within C_8 fluorinated surfactants for AFFF was chiefly used as the ammonium salt (APFO). However specific information on mixtures and formulations is limited in part because of the commercial sensitivities. Queensland Government (2016a) comments on a study from 2014 where 103 different fluorinated compounds were identified within 10 commercial AFFF products available on the Australian market. Barzen-Hanson et al, 2017, conducted analysis on AFFF foams (manufactured by both ECF and telomerisation) produced in the 1980s and 1990s which demonstrate the complexity of AFFF mixtures. The study indicated that more than 240 individual per and polyfluoroalkyl substances (PFAS) can be associated with AFFF, including discovery of forty novel classes of PFAS (30 associated with ECF and 10 associated with telomerisation) and detection of 17 previously reported PFAS. The authors stated that these newly discovered PFAS will pose challenges for effective remediation due to the presumed wide range of solubilities. Systems designed to capture PFOS and PFOA (such as granulated active carbon) will not be effective because shorter-chained substances will likely break through.

198. Following the concerns raised over human health and environment from the use of PFOS, industry largely moved towards C_6 fluorinated technology,[42, 43] although fluorine free alternatives were also developed. This transition is also commented on within the RME. The Swedish Chemicals Agency (2015) comments that C_6 technologies are not based on ECF but rather telomerisation, beginning with perfluoroalkyl iodide as the raw material. Where telomerisation reactions involve perfluorinated compounds it is possible to form C_8 perfluorinated compounds, including PFOA, as a contaminant within C_6 species. The Swedish Chemicals Agency (2015) comments that as much as 20% C_8 can end up within the final stages before clean-up, after which residual concentrations of 0.01% wt/wt may be present in the final commercial product. However, the Swedish Chemicals Agency (2015) also note that studies exist demonstrating that goods marketed as C_6 fluorotelomer products still contain concentrations of C_8 (including PFOA) significantly above trace residual concentrations, in some cases at concentrations with equal amounts of C_6 and C_8. ECHA (2014a) also comments that C_8 fluorotelomer alcohols (FTOHs) used within AFFF can degrade to form PFOA once in the natural environment.

199. Within the EU REACH restriction for PFOA (ECHA, 2015a), an exemption is given for foams mixtures already placed on the market.[44] It was considered that a full and quick replacement with AFFFs based on C_6 technology would not solve the problem of environmental contamination, because of the persistency and mobility of short chain fluorinated alternatives and the difficulty to remediate water contamination. The EU, the REACH restriction allows for the presence of PFOA and PFOA-related compounds as by-product up to a maximum concentration of 25 ppb for PFOA or 1000 ppb for PFOA and PFOA-related compounds in fire-fighting foams placed to market in the EU, which is likely related to trace contamination within fluorotelomer based AFFF. Additionally, Australia maintains a maximum concentration of 50,000 ppb as fluorine within fire-fighting foams (Australia, 2016a), where this limit is exceeded goods must be withdrawn and managed as regulated waste. In addition, Canada provides exemptions for trace quantities of PFOA within to fluorotelomer based AFFFs. Furthermore, in Europe the related

[41] UNEP/POPS/POPRC.13/7/Add.2.

[42] http://www.chemguard.com/pdf/TFPP%20C8%20to%20C6%20Transition%20Bulletin.pdf.

[43] https://www.solbergfoam.com/Technical-Documentation/Foam-Concentrate-Data-Sheets/Arctic-Foam/Brochures/Transition-C8-C6-Foam-Spotlight_F-2017004.aspx.

[44] Under the EU REACH regulation PFOA based fire-fighting foams mixtures placed on the market by or before the 4th July 2020 would be permitted for use. Also concentrated fire-fighting foams mixtures placed on the market before 4 July 2020 to be used or used to produce other fire-fighting foams mixtures are exempted.

compound PFOS had a time limited[45] exemption for foams that were already installed or placed on the market under the EU POPs Regulation.

200. Under the Stockholm Convention goods already placed on the market are exempt from the listing as detailed within item note (ii) of Part 1 of Annex A. However, where fire-fighting foams are marketed as concentrates which are mixed with water at the point of use, it is unclear if these materials can be considered as stockpiles as defined under the Convention.[46] Furthermore responses from industry suggested that an exemption for fire-fighting foams may be needed for stockpiles of in-use goods to aid phase-out. A formal conclusion was not reached at POPRC-13. Therefore, the Committee invited Parties and observers to provide information on chemical composition of mixtures and the volumes of pre-installed fire-fighting foam mixtures in use.

201. Relevant information was submitted by Belarus (2018), Canada (2018), Netherlands (2018a), Sweden (2018), the Fire-Fighting Foams Coalition (FFFC, 2018) and IPEN and ACAT (2018).

4.8.2 Efficacy and efficiency of possible control measures

202. This section provides information on total quantities of PFOA-based fire-fighting foams in use, control measures adopted to limit release and details around the final destruction of fire-fighting foams containing PFOA.

Stockpiles already placed on the market

203. The Fire-fighting Foam Coalition industry association (FFFC, 2004 and FFFC, 2011) provide details of an inventory for PFOS based AFFF fire-fighting foams in the USA as a potential proxy for quantities of PFOA within fire-fighting foam stockpiles assuming that both PFOS and PFOA have been used within C_8 perfluorinated products. The inventory indicates that primary use of PFOS based fire-fighting foams was at installations where oil fires were possible, primarily military installations, petro-chemical facilities and oil refineries. In 2011 the USA PFOS based AFFF inventory records remaining stocks of in-use PFOS based AFFF concentrate as 3.3 million gallons (12.5 million litres) assuming similar quantities of PFOA based AFFF stockpiles. As an alternative estimate Norway (2007) provides commentary on a global inventory for the production of APFO, the primary ammonium salt of PFOA used within AFFF fire-fighting foams. The estimates by Prevedouros et al. (2006) which are quoted in Norway (2007) state that between 1951–2004 global production of APFO was between 3,600–5,700 tonnes. Prevedouros (2006) further comments that the concentration of PFCAs within AFFF foams was between 0.1 and 1% wt/wt of the concentrate, with PFO making the largest proportion. As an alternate estimate, Sontake and Wagh (2014) commented that AFFF concentrates were mixed with water at point of use, with typical application rates of 1, 3 or 6% wt/wt concentrate, which meant that at the point of use (post mixing) PFOS concentrations were at 0.03 – 0.45% wt/wt of the applied foam.

204. Taking a worst case scenario where all PFCA within the AFFF is PFOA/PFOA-related compound, based on active concentrations of 0.1 to 1% APFO within AFFF fire-fighting foams, the global production estimates from Prevedouros et al. (2006), and assumption that all APFO produced is used in fire-fighting foams gives an estimate of global AFFF concentrates containing APFO produced between 1951–2004 as between 309 million litres and 4901 million litres.[47] This would equate to an average annual production of between 6 and 96 million litres of APFO based AFFF concentrate per annum. Assuming the shelf life of AFFF is between 10 and 25 years (FluoroCouncil, 2018), this would equate to remaining global stockpiles of between 60 and 2,400 million litres of APFO based concentrate.

205. Armitage et al. (2006) also quoted by Norway (2007) comments that the estimated environmental emissions of PFOA-related compounds from ECF based manufacture of C_8 perfluorinated AFFF between 1951 and 2004 was 50–100 tonnes, with the largest emissions linked to manufacture of APFO itself (2,060–4,090 tonnes of PFOA between 1951-2004).

206. ECHA (ECHA, 2014a) estimated that 50–100 tonnes of PFOA-related compounds (CAS No: 70969-47-0; C_8-C_{20}-ω-perfluoro telomer thiols with acrylamide) were in use for fire-fighting foams in 2014. This was based on

[45] Under EC 757/2010, fire-fighting foams containing PFOS placed on the market within the EU before 27 December 2006 were allowed to be used until 27 June 2011.

[46] Please note that under para 6 of decision POPRC-13/2 that, a request to the Secretariat has been made to prepare a document on note (ii) of part 1 of Annex A to the Convention and scope of the reference to stockpiles within Article 6 of the Convention and make it available to the Committee for consideration at its fourteenth meeting. This is intended to clarify the Convention scope for goods already placed to market.

[47] The global estimates for APFO manufacture (between 1951-2004) was 3,600 – –5,700 tonnes of APFO, equivalent to 3,600,000 - 5,700,000 kgs. Specific gravity of APFO is 1.163 g/cm (http://www.chemicalbook.com/ChemicalProductProperty_EN_CB7258194.htm) 3,600,000 kg / 1.163 specific gravity = 3,095,442 litres. 5,700,000 kg / 1.163 specific gravity = 4,901,117 litres. PFOS and APFO compounds are present at concentrations between 0.1 – 1–% wt/wt in fire-fighting concentrates. Lowest estimate 309,544,2823,095, litres of APFO as 0.1% Highest estimate 4,901,117,799 litres of APFO as 1% wt/wt.

data from the Norwegian product register and extrapolated to EU-wide quantities based on population, and provides an order of magnitude estimate due to uncertainties arising from the method. The EU report (ECHA, 2014a) assumes similar concentrations for PFOA in mixed foams. For means of comparison with the US inventory and APFO extrapolation, this quantity has been converted into US gallons[48] and litres based on the active concentration of 0.1 – 1% wt/wt in fire-fighting foam concentrates. This would equate to between 1.2 - 23.6 million gallons (4.5 – 89.3 million litres) of fire-fighting foams in Europe containing PFOA-related compounds.

207. Belarus (2018) noted that PFOA based AFFF foams are not used in Belarus, with the main product in use being a Fluoro telomer (C6:2) product called Forafac 1157. The FluoroCouncil (2018b) further comment that Forafac 1157 has been replaced on the market by Capstone 1157, which has a highly purified C_6-based product. Forafac 1157 is also used in Russia.

208. Australia (2018) comments that Australia has never manufactured PFOA or its precursor APFO. However, Australia has imported AFFF foams in the past that contained PFOA-related compounds. The import equated to approximately 48 grammes and 0.6 grammes of PFOA in 2002 and 2003 respectively. Import was discontinued after 2003. A letter from the Airservices Australia (Australia, 2016b) notes that some 260 airports and aerodromes exist across Australia. While efforts have been made to remove PFOS and PFOA based AFFF from service, Airservices Australia acknowledged that some tenants at hangars and fuel depots may still have PFOS/PFOA based foams within fire suppression systems. Discussions were underway to best manage the disposal of these stockpiles. Seow (2013) further comments based on a 2009 NICNAS survey that while imports of new stocks had ceased, stockpiles of C8 perfluorinated AFFF continue to exist in Australia (largely dominated by PFOS); however, Seow (2013) also noted there had been a shift by industry to make use of shorter chain (C_4–C_6) perfluorinated compounds (produced by telomerisation) or perfluorobutane sulphonates (PFBS) in fire-fighting foam.

209. Concentrations of PFASs in AFFF obtained 2012/2013 on the Swiss market (n = 35) were significantly smaller compared to samples (n = 27) taken from fire installations from industrial sites with the last filling date in 1990–2010. The latter demonstrated a majority of PFCAs, PFSAs, FASAs and FASEs with C_{4-11} alkyl chains. In comparison, the mixtures commercially available in 2012/ showed more frequently shorter-chain C_{4-6} PFCAs, 4:2 and 6:2 FTS as well as 6:2 FTOH. The mean concentration declined from 40 to 0.8 ppm (Favreau et al, 2017). Based on a 2005 estimate that quantified the amounts of AFFF stored in Switzerland to be 2,200–2,600 tonnes, the stockpile of PFOA in AFFF may be in the range of 2–100 kg.

210. Alongside the issue of intentional use of PFOA as its ammonium salt (APFO) within existing stockpiles of AFFF, the Swedish Chemicals Agency (2015) and European Chemicals Agency (ECHA, 2014a) highlight the possible continued presence of PFOA as an unintentional contaminant of C_6 fluorotelomers. While the manufacture of C_6 fluorotelomers does not use PFOA in the production process, the telomerisation of perfluorinated compounds can generate C_8 species including PFOA as a by-product. The Swedish Chemicals Agency (2015) comments that at the completion of the production process as much as 20% of the mixture can be C_8 perfluorinated species. After a clean-up phase the final commercial product is expected to contain trace residues at around 0.01%, although the Swedish Chemicals Agency (2015) highlight studies where concentrations found were far higher and could be as much as 50:50% wt/wt C_6:C_8 in some C_6 marketed products. The Netherlands (2018b) comments that data submitted by the Mineraloelwirtschaftsverband trade association, in the public commenting round for PFHxS under REACH, contains data from one PFOS containing AFFF and 14 other foams. The PFOS AFFF also contained PFOA at a concentration of 220 mg/L, approximately twenty times lower than PFOS. Two fluorotelomers based foams analysed as part of the same study (4:2 FTS, 6:2 FTS or 8:2 FTS) contained less than 1.2 mg PFOA/L. Detection limit in these samples varied between 0.010 and 0.050 mg/L (10 and 50 ppb). Seow (2013) comments that industry have worked to refine production and reduce quantities of C_8 species within C_6 products; Seow (2013) however, also notes that many companies have also preferred to remain with their standard processes and mixture of C_6 and C_8. In particular Seow (2013) highlights the presence of acrylamide-based fluorosurfactant (CAS No: 70969-47-0) in some C_6 fluorotelomer products with a chain length of C_8–C_{20} and capacity to act as a PFOA precursor.

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[48] The EU proposal for restriction estimates 50 – - 100 tonnes of PFOA-related compounds, equivalent to 50,000 – –100,000 kgs. Specific gravity of C8-C20-ω-perfluoro telomer thiols with acrylamide is 1.12 g/cm (http://www.interstateproducts.com/fire_fighting/home/ES%20MSDS/ES-818-11.pdf) 50,000 kg / 1.12 specific gravity = 44,640 litres. 100,000 kg / 1.12 specific gravity = 89,300 litres. One US gallon is equivalent to 3.785 litres. 44,640 litres / 3.785 litres per gallon = 11,800 gallons of PFOA-related. 89,300 litres / 3.785 gallons per litre = 23,600 US gallons.

Assuming that PFOA and PFOA-related compounds are used at between 0.1 – 1-% wt/wt in fire-fighting concentrates. 11,890 gallons of PFOA-related = 1.18 – 11.79–1 million US gallons of concentrate. 23,600 US gallons of PFOA-related = 2.36 – 23.59–2 million US gallons of concentrate.

Control measures for environmental release linked to fire-fighting foam

211. The Fire-fighting Foam Coalition (2016) provided details of best practice for use of Class B fire-fighting foams[49] which includes both non-fluorinated and AFFF types of product. The guidance focuses on measures which can be grouped into one of three categories:

(a) Selection of when to make use of Class B fire-fighting foams. The FFFC (2016) comments that Class B fire-fighting foams should only be used when the most significant flammable liquid hazards are identified. For facilities that have potential liquid flammable risks, hazard assessments should be used in advance to investigate whether other non-fluorinated techniques can achieve the required extinguishment and burnback resistance. This includes consideration of the potential shortfalls that alternative methods may have. Furthermore, training exercises should not use fluorinated fire-fighting foams due to concerns over environmental pollution;

(b) Containment of environmental release during use of Class B fire-fighting foams for live incidents. The FFFC (2016) notes the variability of potential incidents and highlights that it is not possible to contain and collect fire run-off in all situations. However, the FFFC (2016) also highlight that runoff from liquid flammable fires will contain a mixture of water, residual hydrocarbon products, fire-fighting foam and therefore loss to environment should be avoided. For facilities that make use of flammable liquids (such as fuel farms and petroleum/chemical processing, airport operations, specific rail transportation, marine and military storage and industrial facilities) the FFFC (2016) best practice guidance states that a firewater collection plan should be developed in advance, and for fixed systems with automatic release triggers containment should be built into the system design. However, it is not clear how many facilities have done this in practice;

(c) Disposal of contaminated runoff and foam concentrate. The FFFC (2016) comments that Class B fire-fighting foam concentrates (which include PFOA based foams) do not carry expiry dates, but generally have a service life of 10–25 years. It is also possible to have testing completed routinely to assess whether the foam in stock still meets requirements. Destruction of Class B fire-fighting foam concentrate should be through thermal destruction. For contaminated fire-water from use of foams the FFFC (2016) guidance highlights that the solution will contain a mixture of chemicals and that thermal destruction is the preferable option. Other options include a combination of coagulation, flocculation, electro-flocculation, reverse osmosis, and adsorption on granular activated carbon (GAC).

212. Klein (2013) provides some further information on the likely costs incurred for the thermal destruction of perfluorinated fire-fighting foams (including PFOS and PFOA). This varies depending on technical approach with plasma-arc facilities likely more expensive than using cement kilns (noting that cement kilns operate at high temperatures).[50] Klein provides a general estimate of cost for Europe as €0.77 per litre of concentrate. For Australia costs within cement kilns ranged from $1–1.5 per litre and in plasma-arc $17–20 per litre. Klein (2013) also comments that the use of GAC, electrocoagulation, or reverse osmosis can be effective at reducing costs as these processes reduce the fluorochemical content. Capital costs for setting up treatment plants using these methodologies varies between €92,000–€230,000. Klein (2013) comments that the significantly high costs of managing disposal for perfluoro based fire-fighting foams had encouraged one major aviation industry operator to switch to fluorine free fire-fighting foams at all of its national airports. Other costs for both plasma-arc facilities and cement kilns include those associated with stringent implementation of BAT/BEP including continuous monitoring to avoid generating further fluorinated or other toxic substances.

4.8.3 Information on alternatives

213. The RME highlighted that many viable chemical alternatives to PFOA-based AFFF are available and commercially in use globally. The paragraphs below are taken from the RME for ease of reference. New reference material is included where indicated.

Short-chain fluorinated alternatives

214. *During the last several years, manufacturers of fluorotelomer-based AFFFs have been replacing long-chain fluorinated surfactants with short-chain fluorinated surfactants (UNEP, 2017). AFFFs based on pure 6:2 fluorotelomers were developed to replace early products based on a mixture of mainly 6:2 and 8:2 fluorotelomers (Klein, 2013; Kleiner and Jho, 2009). DuPont, for example, commercialized two AFFFs based on 6:2 fluorotelomer sulfonamidealkylbetaine (6:2 FTAB) or 6:2 fluorotelomer sulfonamideaminoxide (Wang et al., 2013). Suppliers*

[49] Internationally fires are classified into groups based on the nature of the fire. This in turn defines what kind of fire-fighting media is most appropriate to be used. Class B fires relate to flammable liquids, where fire-fighting foams may be needed to suppress the fire (e.g. oil based fires). http://surreyfire.co.uk/types-of-fire-extinguisher/

[50] BREF, 2010, comments on the general operating conditions within European cement kilns with temperatures up to 2000 degrees Celsius. Materials within sintering zone reach temperatures of 1450 degrees Celsius and retention times of not less than eight seconds.

offering a portfolio of short-chain fluorotelomer-based surfactants include Chemguard, Chemours and Dynax (UNEP, 2017).

215. *Chemical alternatives include C_6-fluorotelomers such as 6:2 fluorotelomer sulfonyl betaine, sometimes combined with hydrocarbons and the 3M product dodecafluoro-2-methylpentan-3-one. The direct release of substances to the environment and the detection of C_6 compounds in the environment including the Arctic, human and wildlife make this use of fluorinated alternatives undesirable* (see UNEP/POPS/POPRC.13/INF/6) (IPEN, 2016). It should be noted that contamination of water from short-chain PFAS is very difficult, if not impossible, to remediate. Holmes (2017) provided further comment on a series of fire industry 'myths', noting that the belief that the alternative short chain C6 and lower PFAS are harmless if released is untrue. Significant evidence has emerged of potential health and environmental effects of short chain PFAS including enhanced mobility, uptake in crops, bioaccumulation, binding to proteins, increasing levels of exposure, difficulty to capture and to clean up once released into the environment.

216. The EU Annex XV restriction report (ECHA, 2014a) highlighted that, while PFOA or PFOA-related compounds are not used in the manufacture of 6:2 fluorotelomer based fire-fighting foams, fluorotelomer based foams can contain trace quantities of PFOA as a by-product. The restriction implemented under the EU REACH regulation applies an exemption for PFOA-based fire-fighting placed on the market on or before 4 July 2020. However, after this date maximum concentrations of 25 ppb for PFOA or 1000 ppb for PFOA and PFOA-related compounds are imposed for fire-fighting foams placed to market in the EU.

217. Mil Tech (2017) (quoted within Canada (2018)) notes that the USA department of defence has amended specifications for use of AFFF fire-fighting foams used in military facilities (including marine), so that AFFF fire-fighting foams must not contain more than 800 ppb of PFOA.

Non-fluorine containing alternatives

218. Development of fluorine free foams capable of managing Class B type fires represents a significant challenge and need for innovation (Cousins, 2016). However, Cousins (2016) and Hetzer (2014) comment that encouraging progress has been made, with some foam manufacturers stating that AFFF is no longer needed. Furthermore Norstrom (2011) comments that commercial airports in Sweden and Norway have replaced PFAS-based firefighting foams with fluorine-free foams because of environmental safety concerns. Since 2008 AFFF is no longer used at fire drills at the Swedavia airports in Sweden and in 2011 Swedavia started to use fluorine-free alcohol-resistant foam (Moussol FF 3/6)" (Nordstrom et al. 2015). *Moussoll-FF 3/6 is degraded to carbon dioxide and water in the environment. It is considered effective in fire suppression required at airports where high safety standards have to be fulfilled. The Swedish Armed Forces began phasing out the use of perfluorinated substances in firefighting foam in 2011 and currently use a fluorotelomer-based firefighting foam, i.e. the substance that is broken down to perfluorinated substances (further details see Swedish Chemicals Agency, 2015). Norwegian airports, military properties and several offshore companies have also introduced fluorine-free foams (Norway Comments on 3rd draft RME).*

219. The Solberg Company developed a high-performance fluorine-free foam concentrate for use on Class B hydrocarbon fuel fires. Recent independent test results published in 2017 (by the Southwest Research Institute) found that the Solberg fluorine-free foam Re-Healing RF3 met the Performance Level B Fire Test Standard of the International Civil Aviation Organization (ICAO). Furthermore, Solberg received the 2014 USEPA Presidential Green Chemistry Award[51] for the innovative development and commercialisation of its fluorine-free foam formulation "Re-Healing." Airservices Australia made the decision to use the Solberg 'Re-Healing RF6 6% foam as the preferred operational firefighting foam at the 23 capital and major regional city airports[52] throughout Australia that are under the auspices of Airservices Australia (Australian Parliament, 2017). Solberg comments that when stored correctly the Re-healing foam has a shelf-life of 10 years (Solberg, 2012).

220. The BAT/BEP Guidance for use of PFOS and related chemicals under the Stockholm Convention on POPs (UNEP, 2017) confirms that non-fluorinated foams exist and are in use. According to a review undertaken by the Queensland Government in Australia, many fluorine-free foams are acknowledged as meeting the toughest amongst the firefighting standards and exceeding film-forming fluorinated foam performance in various circumstances and that fluorine-free foams are widely used by airports and other facilities including oil and gas platforms (see Queensland Gov., 2016b). According to the Swedish Armed Forces it is difficult to find fluorine-free alternatives which meet specific safety requirements (see Swedish Chemicals Agency, 2016).

221. Castro et al (2017) provides comments on the comparable performance between AFFF (telomer based) and FFF (fluorine free) products, which were based on 80 tests carried out by Auxquimia. For heptane and diesel based fires fluorine free foams were 6-7% slower than AFFF at bringing fires under control. For gasoline and jet A1 based

[51] http://www.solbergfoam.com/getattachment/2819d8c8-f365-4da5-ba4b-8e6f1a2bd5cb/Presidential-Award-Bestowed-on-Solberg.aspx.

[52] Noting that 260 airports and aerodromes exist across Australia in total (Australia 2015).

fires, fluorine free foams were 50-60% slower than AFFF at bringing fires under control. However, where application rates were increased (from 2.31/min/m^2 to 3.75/min/m^2) for fluorine free based products similar levels of performance compared to AFFF were achieved. Castro et al (2017) goes on to hypothesis why this difference may be the case, noting that fluorinated compounds perform a variety of roles within the foam, one of which is oil repellence allowing foams to spread and control the fire for liquid fuels. Castro comments that fluorine free products lack this quality, but by increasing application rates the fluorine free foam can spread and cover liquid fires more quickly.

222. According to the Fire-fighting Foam Coalition (FFFC) AFFF agents containing fluorotelomer-based fluorosurfactants are the most effective foam agents currently available to fight flammable liquid fires in military, industrial, aviation and municipal applications. Test data provided by the United States Naval Research Laboratories (NRL, 2016) showed that, in pool fire tests, an AFFF agent achieved extinguishment in 18 seconds compared to 40 seconds for the fluorine-free foam. However, an alternate study from 2004 (Lerner, 2018) with the US Navy commented that based on testing of AFFF based foams from 3M and fluorine-free alternatives that similar rates were achieved for putting out fires. The fluorine-free alternative put out fires within 39 seconds, while AFFF ranged from 25 to 36 seconds.

223. In foam degradation tests, fluorine-free foam degraded after 1-2 minutes, while the AFFF lasted 35 minutes before it has been degraded. The FFFC does not support the opinion that AFFF agents are no longer needed and recommends the use of AFFF only in specific circumstances where a significant flammable liquid hazard occurs and that all available measures to minimize emissions to the lowest possible level should be implemented when using AFFF agents (FFFC, 2017). However, blockage factors (i.e. vapour suppression) were indistinguishable between a fluorine-free-foam and two AFFFs tested (Williams et al. 2011). Alternatively, information provided by The Solberg Company (Norway, 2018 personal comms) confirm that fluorosurfactant- and fluoropolymer-free firefighting foam used to effectively extinguish fuels with no environmental concerns for persistence, bioaccumulation or toxic breakdown have shown to perform the same ability to extinguish Class B fires as traditional AFFF.[53] Airports and offshore companies around the world have introduced fluorine-free foam and are satisfied by the performance.

224. Fluorine-free foams certified to different ICAO levels (required for use at civilian airports) are available on the market (see FFFC, 2017) and are already introduced at airports in practice. For example, the UK Civil Aviation Authority notes that fluorine-free foams are ICAO Level B approved and found that fluorine-free foams were just as efficient as AFFF in large-scale fire tests; while the Copenhagen Airport replaced AFFF with Solberg RF Re-Healing foam for environmental reasons[54]. Manufacturers of fluorine-free foams that are currently on the market include: National Foam (Jetfoam—used in aviation applications; and Respondol—a Class B product); Bioex (Ecopol); Fomtec (Enviro 3x3 Plus); Solberg (Re-Healing Foam RF6/RF3); and Dr. Sthamer (Moussol F-F3/6), Auxquimia (Unipol); Vsfocum (Silvara); Biosafety Technology (Trident); and 3F (Freefor SF, Hyfex SF, Freedol SF).

225. Bioex asserts that their Ecopol, Bio For, Bio T, and Bio Foam fluorine-free foams are as effective as the best AFFF foams and that they obtained the best 1A performance classification under EN 1568-3 standard (certified 1 A/freshwater and 1 A/seawater). Solberg Re-Healing RF3 Foam meets fire performance test criteria of Underwriters Laboratory (UL Standard 162), Underwriters Laboratories of Canada (Standard S564), FM Approval Standard 5130, European Standard EN 1568 Part 3 and International Civil Aviation Organization Level B.[55]

226. The Institute for Fire and Disaster Control Heyrothsberge in Germany tested six fluorine free alcohol resistant firefighting foams and one PFAS containing foam for their ability to extinguish fires of five different polar liquids. The authors conclude that there are fluorine-free foams available which show a similar performance compared with PFAS containing foams (see Keutel and Koch, 2016).

227. Only very limited data exists to allow a comparison of costs of non-fluorinated fire-fighting foams against short-chain fluorotelomers. The RME provided data from 2004 as a price comparison, but this is likely to be outdated. While data on direct price comparison has not been identified other metrics provide an indication of issues affecting cost. The FFFC (2018) commented that short-chain fluorotelomer based AFFF has a shelf-life of 10-25 years, while a manufacturer of fluorine free alternatives (Solberg, 2012) quotes a shelf-life of 10 years. Comments from the Netherlands (2018b) note that, based on discussions with a fire brigade in the Netherlands, fires at private facilities are rare, and where AFFF should not be used for training, it can mean that stockpiles reach full life-expectancy without use, meaning shelf-life is an important consideration. Castro (2017) comments that for application of foams, particularly on petrol and jet A1 fuels that significantly more fluorine free foam (from 2.31/min/m^2 to 3.75/min/m^2) foam is needed to bring fires under control at an equivalent speed to AFFF fluorotelomer. IPEN commented in the RME however that when considering cost the wider environmental costs should also be taken into account. This would include *the internalized costs of continued reliance on fluorosurfactant foams, including the costs of*

[53] http://www.solbergfoam.com

[54] https://www.solbergfoam.com/getattachment/b706ff4d-1f47-4030-bd7d-cc8762d3bfed/CAFS-FFF-In-ARFF.aspx

[55] https://www.solbergfoam.com/getattachment/b706ff4d-1f47-4030-bd7d-cc8762d3bfed/CAFS-FFF-In-ARFF.aspx

groundwater remediation, contamination of aquatic environments, subsistence and commercial fisheries, and environmental and public health (IPEN Comments on 2nd draft RME). Lifetime costs for using AFFF, fluoroprotein (FP), or film forming fluoroproteins (FFFP) far outweigh those of fluorine-free foams because of legal and financial liabilities of using a fluorochemical based foam (see Queensland Gov., 2016a and 2016b) as indicated above which include infringement of operating license conditions, reputational and brand image damage (see Klein 2013). Increasing evidence suggests that fluorochemical contamination of groundwater is an ongoing serious issue impacting agriculture, fisheries, property prices, with considerable political and public concern fallout resulting in hugely expensive and damaging and legal challenges. Remediation costs are still substantial, especially off-site, compounded by high analytical and consultancy costs in the case of environmental contamination with fluorinated breakdown products from an AFFF, FP or FFFP (see e.g. Klein 2013).

228. The evidence presented within the RME suggests that chemical alternatives to PFOA based AFFF exist and are actively in use globally.

4.8.4 Information on impacts on society

229. The RME highlighted concerns related to the dispersive and direct way in which fire-fighting foams are used. The RME also noted that the continued use of PFOA in firefighting foams would result in the ongoing contamination of groundwater and soil surrounding facilities where PFOA-based AFFF was used (mainly military sites and airports). The RME provides examples of such cases with an indication of the magnitude of the contamination and remediation costs. As part of the request for information, the paragraphs below include further details on ground contamination linked to use of PFOA-based AFFF fire-fighting foam.

230. Military.com (2017) (quoted within IPEN, 2018) provides details of discussions held in the US senate regarding around 400 military facilities where PFOS and PFOA based fire-fighting foams had been previously used and lost to the environment causing ground contamination such as that Fairchild Air Force base. Total estimated remediation costs for ground contamination are cited within the article as being as high as USD$2 billion dollars.

231. Klein (2013) provides examples of a number of cases of groundwater contamination at facilities (military, airports and petroleum refineries) where perfluoroalkyl-containing (chiefly PFOS) fire-fighting foams have been used for training or real cases of fire. In particularly Klein refers to a case study at US military fire training grounds where PFOS had been previously used, and even 10–15 years after the use had ceased monitoring found that groundwater would still contain high concentrations of fluorotelomer (14.6 mg/L fluorotelomer sulfonate). Another case study at Jersey Airport, Jersey Island, report that the use of PFOS-based AFFF on fire training grounds contaminated the island's aquifer and drinking water. Remediation costs were estimated to be between £3.7 to £30 million pounds sterling (based on 1999–2000 prices) dependent on options selected. This included the potential removal and destruction of soil to a depth of 30 metres and reconstruction of the site.

232. Cousins (2016) (quoted within IPEN (2018)) further highlighted that the costs of cleaning up the contaminated site is only one of many costs associated with the legacy contamination from PFAS-containing firefighting foams (both long and short chain); Others include cost of analytical monitoring of PFAS, destruction of old stockpiles, clean-up of equipment contaminated by previous use, costs of developing and commercializing sustainable alternatives, funding new research, health costs, legal costs, etc. Most of these costs will be borne by taxpayers, as it is challenging and often costly to identify the principal responsible party or parties in practice. However, in environmental law many countries have adopted the "polluter pays principle" to make the party responsible for the pollution responsible for cleaning it up. It is regarded as a regional custom because of the strong support it has received in most OECD countries and in the EU as well as in Norway. It is also a fundamental principle in US environmental law (Norway, 2018).

233. Recognizing the serious public health implications associated with contamination of drinking water sources by PFAS firefighting foams and the need to prevent further harm, policymakers in Washington State (USA)[56] recently enacted the first state legislation in the USA that prohibits the use of PFAS-containing firefighting foams for training purposes beginning on July 1, 2018 and prohibits the sale of PFAS-containing firefighting foams for use in Washington State beginning on July 1, 2020. Furthermore, Land et al. (2018) comment on temporal trends of perfluoroalkyl acids in humans and in the environment, stating: "In regions where regulations and phase-outs have been implemented, human concentrations of PFOS, PFDS, and PFOA are generally declining, while previously increasing concentrations of PFHxS have begun to level off".

234. Patrick Breysse,[57] Director of the US Centers for Disease Control's National Center for Environmental Health, described the contamination of drinking water by perfluorinated chemicals in AFFF as "one of the most seminal public health challenges for the next decades." Unlike other persistent, bioaccumulative toxic chemicals such as PCBs

[56] https://toxicfreefuture.org/new-law-protects-drinking-water-firefighters-toxic-perfluorinated-chemicals/

[57] https://www.theguardian.com/australia-news/2017/oct/18/toxic-firefighting-chemicals-the-most-seminal-public-health-challenge

and dioxins, PFAS are highly water soluble and do not break down in the environment. Of particular concern, perfluoroalkyl acids that reach groundwater "may remain there indefinitely, impacting drinking water sources for generations to come." In the United States alone, the drinking water of more than six million people in many communities throughout the country has been found to contain highly fluorinated chemicals at concentrations of concern. Cousins (2016) recommend a precautionary approach that respects the "design for degradation" principle of Green Chemistry, stating that "according to this reasoning, society should replace all PFAS-based fire-fighting foams with non-persistent fire-fighting products, given that they can lead to poorly reversible exposures." The precautionary approach is consistent with that mandated by the Stockholm Convention.

4.8.5 Other considerations

235. ECHA (ECHA, 2015a) allows a derogation for existing PFOA-based fire-fighting foams mixtures (including the concentrated ones) placed on the market on or before 4 July 2020, which allows further use for a period of 20 years, taking into account the shelf life. This derogation is consistent with the exemption for foams already in use, and will avoid the need for early replacement of exempted foams.[58] IPEN commented within the RME and discussions at POPRC-13 that the normal lifetime of firefighting foam varies considerably with temperature and storage conditions. According to them, 20 years is an inappropriate length of time for continued dispersive use of POPs, a use which has led to massive contamination of groundwater in many countries. The FFFC (2016) best practice guidance commented that PFOA-based fire-fighting foam does not have an expiry date but will have a shelf life of 10–25 years. The Netherlands (2018b) noted from discussions with colleagues at the Bilthoven fire brigade, NL, the safety manager for the Gelderland region and their own experience that the active use of AFFF at private installations (e.g. airports, refineries, and military sites) is rare and that stockpiles of AFFF may be likely to reach the 25-year shelf life without use. Solberg (2012) comment that their fluorine-free fire-fighting foam has a shelf-life of 10 years. The Netherlands (2018b) further comment that where fires at private installations (e.g. airports, refineries, and military sites) are rare, the shelf-life of fire-fighting foams is an important consideration for costs.

4.8.6 Synthesis of information

236. Fluorinated fire-fighting foams have been used as an effective means of fighting Class B (oil) fires, with a preference in the past for C_8 technologies developed by ECF (Swedish Chemicals Agency, 2015). This included PFOS, which is now a POP under the Stockholm Convention, and PFOA, primarily used as the ammonium salt (APFO). Where human health and environmental concerns over C_8 perfluorinated compounds exist, industry moved to shorter chain C_6 technologies developed through telomerisation (Swedish Chemicals Agency, 2015). While C_6 fluorotelomers are not manufactured using PFOA, final goods can contain PFOA as an unintentional by-product. The Swedish Chemicals Agency (2015) and Seow (2013) suggest that this is typically a trace residue but also highlight studies exist demonstrating that the quantity of C_8 species (including PFOA) within C_6 technologies can be present at greater concentrations, potentially up to 50:50% wt/wt and can contain PFOA precursors such as acrylamide-based fluorosurfactant (CAS No: 70969-47-0).

237. Only limited information exists to quantify the PFOA-based fire-fighting foams already placed on the market. ECHA (ECHA, 2014a) suggested that 50-100 tonnes of PFOA-related compounds (CAS No: 70969-47-0) were in-use within fire-fighting foams in 2014, which has been calculated to be equivalent to 0.2–2.3 million US gallons (0.75–8.7 million litres) of concentrate for AFFF. The FFFC (2011) inventory of PFOS concentrates quotes 3.3 million US gallons (12.5 million litres) in use for 2011. This assumes that similar quantities of PFOA based concentrates were in use. Alternatively estimates by Prevedouros et al. (2006) state that between 1951–2004 global production of APFO was between 3,600–5,700 tonnes, assuming all of this was used in fire-fighting foams equates to between 51–490 million litres of APFO concentrate manufactured globally between 1951– 2004.The FFFC (2016) developed a best practice guidance for use of class B fire-fighting foams, which include PFOA based fire-fighting foams. This included selection of foams only where most needed and avoiding the use of class B fire-fighting foams for training due to concerns over environmental pollution. The best practice also included forward planning for facilities that use flammable liquids to put in place capture and containment systems for runoff. It is not clear how many facilities have implemented this part of the guidance. The FFFC (2016) guidance does also indicate the variability of incidents and that capture of runoff is not possible in every situation. The guidance also provides details on suitable destruction for fire-fighting runoff and foam concentrates; with thermal destruction as the preferred option. Klein (2013) provides indicative costs for destruction of foam concentrates at around €0.77 per litre or $1–1.5 Australian dollars per litre.

238. The RME details that multiple alternatives to PFOA based fire-fighting foams are already commercialised and readily available. This includes fluorinated options based around fluorotelomers (C6:2) and fluorine free alternatives. ECHA (ECHA, 2014a) noted that the manufacture of fluorotelomer based fire-fighting foams can contain trace

[58] UNEP/POPS/POPRC.13/7/Add.2.

amounts of PFOA as a by-product. The restriction sets limits of 25ppb for PFOA and 1000ppb for PFOA and PFOA-related compounds.

239. The RME provided details regarding groundwater contamination with perfluorinated fire-fighting foams (primarily PFOS) indicating the significant costs and efforts required to clean up contaminated sites and potential long-lasting effects of contamination. This included a case on the island of Jersey, where clean up options for contamination of an aquifer with PFOS based foams was in the order of £3.7–£30 million pounds. Other examples from the USA highlighted cases where groundwater contaminated with PFOS was still able to produce foam when extracted 10–5 years after contamination.

240. Finally, ECHA (ECHA, 2015a) discusses the length of the derogation needed for PFOA based fire-fighting foam placed on the market. Under the EU REACH restriction, a derogation was granted for fire-fighting foams (including concentrated solutions) placed on the market before 4 July 2020. Considering the shelf-life of fire-fighting foam mixtures, this means that they could be still used for 20 years. A similar exemption could be adopted for the Stockholm Convention, although the continued dispersive use of a POP would not be consistent with the objectives of the Convention. IPEN (2018) commented that the life span of foams varied depending on climate and storage and therefore a 20-year derogation would not be acceptable for the Stockholm Convention. The FFFC (2016) state that foams do not have an expiry date but have a shelf life of 10–25 years.

4.8.7 Conclusion

241. Based on the information compiled and reviewed within the RME, the size of in-use stockpiles for PFOA based fire-fighting foams may be significant, while PFOA and PFOA-related compounds can also be present as a by-product in shorter chain C_6 telomer technologies. Concerns have also been highlighted about the mobility and potential environmental impacts of shorter chain perfluorinated compounds in fire-fighting foams including high costs of clean-up (Klein, 2013). The Committee should consider whether the non-fluorinated alternatives already commercialised and in use can replace the fluorine-based AFFFs for all uses and the issues surrounding existing stockpiles as two separate elements. On this basis, the Committee should formulate a recommendation that covers both PFOA and PFOA-related compounds within fire-fighting foams and existing stockpiles.

5 Synthesis of information

5.1 Summary of information and concluding statement for uses

242. The Committee invited Parties and observers, including the relevant industries, to provide information that would assist the possible defining by the Committee of specific exemptions for production and use of PFOA, its salts and PFOA-related compounds. Table 5.1 in appendix II to the present document provides a summary of key information within the current document and concluding statements.

5.2 Discussion on listing in Annex A/B

243. The invitation to Parties and observers to submit information on the additional uses discussed within the current document is intended to assist the Committee in reaching a decision on whether exemptions are needed, and whether those exemptions should be a specific exemption (time-limited) or acceptable purpose (non-time limited). Based on a review of the information submitted and the RME, work is already ongoing for many of the applications identified to develop and commercialise alternatives to PFOA, its salts or PFOA-related compounds, with a number of alternatives already in use.

244. Furthermore, the European restriction for PFOA, its salts and PFOA-related compounds (EU 2017/1000 amending EC 1907/2006) grants only one use, implantable medical devices, with a non-time limited exemption. Canada also has a non-time limited exemption for fire-fighting foams (RME). The information from MedTech Europe (2018) suggests the transition for implantable medical devices will be complete by 2030. For fire-fighting foams, alternatives are already in use globally (see section 4.8) with the main obstacle being economic management of in-use stocks.

245. On the basis of the information reviewed and compiled within the current document, the exemptions that may be required all relate to time-limited options, which best match specific exemptions under the Convention with no uses identified needing an acceptable purpose. On that basis, it can be concluded that a listing of PFOA, its salts and PFOA-related compounds in Annex A is most appropriate.

Appendix I

Overview of regulatory risk management approaches, their chemical scope and exemptions for uses related to PFOA, its salts and PFOA-related compounds in Canada, the EU and Norway

(for details see Canada, 2016c, European Commission, 2017 and Norway, 2016)

Table 3 of the RME set out in document UNEP/POPS/POPRC.13/7/Add.2

	Canada	EU	Norway
	Prohibit manufacture, use, sale, offer for sale or import of the substances and products containing these substances	Prohibit manufacturing, use or placing on the market (1) as substances, as constituents of other substances and (2) articles or any parts thereof containing one of the substances	Prohibit to manufacture, import, export and make available on the market (1) textiles, carpets and other coated consumer products that contain the substances and (2) consumer products that contain the substances
Chemical scope	PFOA and its salts; Compounds that consist of a perfluorinated alkyl group that has the molecular formula C_nF_{2n+1} in which n=7 or 8 and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom; Perfluorocarboxylic acids that have the molecular formula $C_nF_{2n+1}CO_2H$ in which $8 \leq n \leq 20$, and their salts; Compounds that consist of a perfluorinated alkyl group that has the molecular formula C_nF_{2n+1} in which $8 \leq n \leq 20$ and that is directly bonded to any chemical moiety other than a fluorine, chlorine or bromine atom. (see Canada, 2016c)	PFOA and its salts; Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula C_7F_{15}- directly attached to another carbon atom, as one of the structural elements. Any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula C_8F_{17}- as one of the structural elements. Exclusions: C_8F_{17}-X, where X= F, Cl, Br; C_8F_{17}-C(=O)OH, C_8F_{17}-C(=O)O-X' or C_8F_{17}-CF_2-X' (where X'=any group, including salts). Does not apply to PFOS and its derivatives, which are listed in Part A of Annex I to Commission Regulation (EC) No 850/2004 (see European Commission, 2017) PFOA<25ppb, related compounds <1,000 ppb	PFOA and individual salts and esters of PFOA (CAS No: 335-67-1, 3825-26-1, 335-95-5, 2395-00-8, 335-93-3, 335-66-0, 376-27-2, 3108-24-5) (See Norway, 2016)
Exemptions for photo-imaging	Photo media coatings until 31 December 2016 Since then partially captured under exemptions for manufactured items	Photographic coatings applied to films, papers or printing plates	Photographic coatings for film, paper or printing plate until 2016

	Canada	EU	Norway
Exemptions for semiconductor industry	Partially captured under exemptions for manufactured items	- Equipment used to manufacture semiconductors (until 4 July 2022); - Photo-lithography processes for semiconductors or in etching processes for compound semiconductors; - Ssemiconductors or compound semiconductors.	Adhesives, foil or tape in semiconductors until 2016
Exemptions for firefighting	Aqueous film-forming foams used in firefighting applications	- Concentrated firefighting foam mixtures that were placed on the market before 4 July 2020 and are to be used, or are used in the production of other firefighting foam mixtures; - Firefighting foam mixtures which were: a) placed on the market before 4 July 2020; or b) produced in accordance with paragraph 4(e), provided that, where they are used for training purposes, emissions to the environment are minimized and effluents collected are safely disposed of.	Not covered by the restriction
Exemptions for medical uses	Partially captured under exemptions for manufactured items	- Medical devices (until 4 July 2032); - Production of implantable medical devices within the scope of Directive 93/42/EEC.	Medical devices are exempted from restrictions
Exemptions for textiles	Partially captured under exemptions for manufactured items	- Textiles for the protection of workers from risks to their health and safety (until 4 July 2023); - Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment (until 4 July 2023).	Textiles for consumer use are restricted when PFOA concentration is above 1ug/m^2 for any part of the product.
Exemptions for inks	Water-based inks until 31 December 2016	Latex printing inks (until 4 July 2022)	
Exemptions for nano-coating	Partially captured under exemptions for manufactured items	Plasma nano-coating (until 4 July 2023)	
Exemptions for food packaging	Partially captured under exemptions for manufactured items		Food packaging, food contact materials are exempted from this regulation

The scope of the regulatory actions presented in the Table above differ in scope compared to each other and the scope set out in the RME based on the principles of the Stockholm Convention. The RME covers degradation to PFOA from long-chain PFASs with more than eight perfluorinated carbon atoms except for those explicitly excluded in the definition of PFOA-related compounds as they do not degrade to PFOA under natural conditions. This goes beyond the EU risk management approach which does not cover the degradation to PFOA from long-chain PFASs. The degradation from long-chain PFASs is also not considered in the Norwegian risk management approach. The Canadian risk management approach also applies to long-chain PFCAs, their salts, and their precursors. However, long-chain PFASs have been included on Norway's priority list of substances whose release to the environment should be eliminated by 2020, and they are included in the US Stewardship Program (IPEN Comments on 2nd draft RME).

A general definition of "long-chain PFCAs" ($C_nF_{2n+1}COOH$, $n \geq 7$) is provided by the OECD (OECD, 2017). As a result of the existing production processes, fluorotelomer-based substances have been generally manufactured as mixtures of homologues with a range of perfluoroalkyl chain lengths (for examples, see DuPont, 1998), including those that have more than eight perfluorinated carbon atoms.[59] Therefore, the information provided in the RME covers to a certain extent also those fluorotelomer-based substances with longer chain PFAS (longer than 8:2).

[59] Commercial products containing primarily >99% of one individual homologue may exist, this requires additional purification processes.

Appendix II

Summary of evaluation of uses and conclusions regarding specific exemptions for PFOA, its salts and PFOA-related compounds

Table 5.1 Summary of evaluation of uses and conclusions regarding specific exemptions for PFOA, its salts and PFOA-related compounds

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
Membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment	Information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects	Unknown	The RME for PFOA highlights the need for further information to justify a possible exemption for these uses. In particular, the Committee requested additional information on the scope of the applications, used amounts, availability of alternatives and socio-economic aspects. Limited information on the scope of the applications and the availability of alternatives has been submitted. However, alternatives including non-fluorinated alternatives for these uses are in current use. No relevant information has been provided or could be identified on used amounts in relevant applications. Used amounts in specific applications and related information which would also enable the socio-economic aspects and information on the possible non-availability of alternatives to be further evaluated would be required to justify exemptions. In summary, there is a lack of information about specific uses and amounts but indication that alternatives are available for a variety of uses.	Based on the evaluation of available information an exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment should not be considered.
Transported isolated intermediates in order to enable reprocessing in another site	Information on the quantities used, extent of transport and risks, and use	50–100 tonnes	IPEN and ACAT and the FluoroCouncil provided relevant information in response to the current information request. Both submitters and Norway commented on the first draft. IPEN and ACAT also expressed concerns that an exemption for transported isolated intermediates could "open the door to waste dumping in	Archroma's proposal requires both an exemption for PFOI transport as an intermediate and the reclassifying of 1-H-PFO as not being a PFOA-related compound. Based on the evaluation of available information a time limited

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
than the production site			developing and transition countries under the guise of "reprocessing"." The FluoroCouncil requests an exemption on behalf of its member, Archroma for the transport of PFOI, an unintended side fraction in the production of C_6 fluorotelomers, as a transported isolated intermediate. Archroma argues that they cannot reprocess PFOI, a PFOA-related compound, on-site as a closed-system site-limited intermediate. PFOI is currently transported in closed barrels to a facility in South Korea where iodine recovery and reprocessing to TFE and HFP, take place under closed system conditions. Archroma is developing a method for on-site iodine extraction, a prerequisite for reprocessing PFOI. A transitional exemption for the transport of PFOI as a transported isolated intermediate would be necessary, since the process will not be available on-site before the entry into effect of the Convention's provisions on PFOA. Moreover, the process leads to the production of 1-H-PFO, that also falls under the definition of a PFOA-related compound (questioned by the FluoroCouncil) and is therefore not a viable solution, if 1-H-PFO is considered a PFOA-related compound. Archroma submitted information about risk management measures during taken to avoid releases and informed that all steps of the process covered by the exemption request apply the best available techniques and are conducted in closed systems with (1) no contact with water and (2) incineration of off-gases. The only exception relates to the loading/unloading of containers used for the transport of the PFOI fraction, where they claim that strictly controlled conditions are in place. IPEN and ACAT (2018) note that the proposal to exempt transport of isolated intermediates at the global level undermines the integrity of	exemption could be considered for the use of PFOI (Perfluorooctane iodide) as isolated intermediate in order to enable reprocessing to TFE (tetrafluoroethylene) and HFP (hexafluoropropylene) in another site than the production site. Based on the information provided, the Committee has to decide whether a specific exemption should be given.

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
			the Stockholm Convention. The Convention limits generic exemptions relating to intermediates to strictly closed-system site-limited intermediates that are chemically transformed in the manufacture of other chemicals that, taking into consideration the criteria in paragraph 1 of Annex D, do not exhibit the characteristics of POP. IPEN and ACAT (2018) add that PFOI is a PFOA-related compound that is predicted to become an Arctic contaminant, disrupts the endocrine system, and may cause long lasting harmful effects to aquatic life.	
Medical devices	Information on specific applications/uses and timelines foreseen as needed for potential related exemptions	Unknown	MedTech (2018) and Euromed (2015) commented that gathering information on specific applications was challenging and indicated that PFOA would chiefly be present as a by-product of PTFE manufacture. PFOA has been used as an emulsifier. MedTech (2018) also provided a summary of generic potential uses. To ease the decision at the COP, IPEN and ACAT (2018) commented that a specific list of applications is needed to help maintain clarity and enforcement of the Convention. ECHA (ECHA, 2015) estimated in use quantities of <1kg in the EU extrapolated to <5kg globally. ECHA (ECHA, 2015). As part of the REACH restriction process an exemption was granted for non-implantable medical devices of 15 years to allow phase-out and development of alternatives. The RME noted that PFOA free PTFE options have already been developed, passed stringent regulatory requirements and have been commercialised in some geographies. The ECHA Annex XV restriction report comments that 70% of global PTFE production is now PFOA free under the PFOA product stewardship programme chaired by the US EPA which covers Japan, Europe and the USA. However many medical devices are manufactured outside of these areas (MedTech, 2018).	Specific lists of applications for medical devices using or containing PFOA have not been identified. Although information on a generic basis has been included. Quantities of PFOA still in use and required up to the point of transition are low compared to other uses such as fire-fighting foams, though even small amounts of PFOA will be persistent, can travel long distances from point of release and have the capacity to bioaccumulate. Alternatives to PFOA based PTFE have been developed and commercialised in at least some geographies. Potential issues with stringent medical regulations may also delay the transition processes and this would

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
				suggest that a time-limited exemption may be appropriate.
Implantable medical devices	Information on the quantities used, extent of transport and risks, and use:	20g for EU extrapolated to 100g globally	ECHA (ECHA, 2015a) indicates that amounts of PFOA and PFOA-related compounds related to this use are extremely low. – Further information and data on quantities used, extent of transport and risks, and use of PFOA in implantable medical devices was not provided in response to the request for information. Implantable medical devices, such cardiovascular devices catheters and guidewires, can contain PTFE made from PFOA (MedTech 2018). However, PTFE can be made without PFOA and alternatives are reportedly now commercially available, approved by US FDA, and are a feasible and effective alternative to the use of PFOA.	Cost competitive alternatives, such as PFOA free PTFE products have already undergone clinical testing, been approved and have been implemented for use in some specific medical implant devices. However, replacement of PFOA in all types of implantable medical devices is not known to have taken place and clinical testing of any alternatives will be necessary on a case by case basis (taking many years) to establish the feasibility and effectiveness of any alternative prior to being medically approved. Further detail on specific applications is needed before the Committee should consider an exemption for PFOA and PFOA-related compounds in implantable medical devices including whether a specific exemption could be narrowed to a specific use such as cardiovascular implantable medical devices. Possible time-limited exemptions for this use therefore could be considered.

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
Photo imaging sector	Information relevant for paper and printing sector and use in developing countries;	Unknown	I&P Europe (2018) state that non-perfluorinated alternatives have successfully replaced most uses in the imaging and printing industry and the move to digital imaging will replace the need for PFOA. PFOA use in photo-imaging has been reduced by more than 95% worldwide since 2000 (I&P Europe) due to reformulation and discontinuation of PFOA-related compounds. Indeed, digital imaging has been adopted in developing countries in favour of hardcopy printing (IPEN and ACAT, 2018). The IAEA and WHO provided a further example of the transition to digital technologies within developing and transition countries, noting in particular that the rapid adoption of digital technology in healthcare results from "efficiencies inherent in digital capture, storage and display and the competitive cost structures of such systems when compared to alternatives involving film." Further information on use of PFOA or PFOA-related compounds in other industry sectors was not received in response to the call for information. The emissions from the small number of ongoing uses by the photo-imaging industry have been assessed by a number of competent authorities in the EU, including ECHA, and determined not to pose a relevant risk to the environment or human health (I&P Europe, 2016).	Based on the existing and rapid transition towards digital imaging, the wide use of digital techniques in developing and transition countries, and the further reduction in use of PFOA in this sector, no exemptions for photographic coatings applied to paper and printing plates should be considered necessary.
Automotive industry	Information on spare parts	Unknown	The Canadian automotive association, CVMA, requested specific exemptions for automotive service and replacement parts as well as for current production vehicles. The request for exemption is also supported by industry associations ACEA (Europe) and SIAM (India). According to CVMA, the industry has been proactively phasing out PFOA use for some time. However, service and replacement parts might still contain PFOA. According to CVMA, these parts represent a small percentage of PFOA use and will decrease naturally over time as the vehicle fleet turns-over.	Based on the review of updated information a time limited exemption could be considered for automotive service and replacement parts and vehicles. However, additional information should be made available by the automotive industry. No conclusive information has been provided on the specification of

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
			Automotive manufacturers reportedly need to ensure the availability of original equipment and spare parts to satisfy customer demand. Further, according to the Canadian automotive industry, a key obstacle in a complete phase-out of PFOA in automotive service and spare parts appears to be the prohibitive costs. However, no information on possible cost implications has been submitted. In addition, the Canadian automotive industry has concerns regarding practical challenges related to numerous CAS numbers of affected substances. This has also been expressed by ACEA and SIAM, stating that a considerable amount of time would be required to collect relevant data. In contrast to the request for exemption, IPEN and ACAT stipulate that key automotive industry associations have notified company members and suppliers that PFOA will be listed under the Stockholm Convention as well as being regulated in the EU and that these substances should be substituted. The automotive industry also notes that, most suppliers producing relevant articles no longer use PFOA or other long-chained perfluorinated chemicals. In the past PFOA has been used to make fluoropolymers used in automotive applications but several companies have alternative emulsifiers so that PFOA has been eliminated in this class of automotive products. In summary, the Committee requested specification of relevant automotive service and replacement parts as well as sound justification as to why an exemption is required. Limited information has been submitted on specific applications, socio-economic aspects and the availability of alternatives. No conclusive information was submitted so far on the specification of relevant automotive service and replacement parts and on the quantities of relevant substances used in different applications. Further information such as used amounts in different parts is considered necessary to justify a recommendation for an exemption. CVMA indicates in their recent	relevant automotive service and replacement parts (specific parts or categories of parts) and on the quantities of relevant substances used in different applications. Information such as amounts used in different parts is considered necessary to justify a consideration of a recommendation for an exemption. Further information on time for phase-out, estimation of economic impacts, alternatives in place and retrofitting capacity would support further discussions at international level.

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
			submission that they are currently working to see if any further information can be provided.	
Fire-fighting foams	Information on chemical composition of mixtures and the volumes of pre-installed amount of fire-fighting foam mixtures	APFO potentially between 10–230 million litres of AFFF concentrate. PFOA and PFOA-related compounds as by-product in C_8 assumed as 50–100 tonnes of concentrate for EU.	Perfluorinated compounds have been used within fire-fighting foams as they prove effective against liquid fuel fires (Class B) (ECHA, 2014a). In the past C_8 based perfluorinated compounds have been used including PFOS and PFOA. Seow (2013) reported that the ammonium salt of PFOA (APFO) was the main intentional use of PFOA produced through ECF. Only limited information has been identified stockpiles for in-use intentionally added PFOA fire-fighting foams. The EHC (2011) estimated 3.3 million gallons of PFOS based firefighting concentrates in use for the USA in 2011, which is indicative of PFOA based stocks. Conversely Norway (2007) report on a global inventory for APFO manufactured between 1951–2004, with between 3,700–5,600 tonnes produced. Prevedouros (2006) further comments that the concentration of PFCAs within AFFF foams was between 0.1 and 1% wt/wt of the concentrate. Assuming a worst case that all of the 0.1 – 1% wt/wt was APFO would equate to between 309 and 4,907 million litres of concentrate produced between 1951 and 2004. Based on annual average production and shelf-life of 10 – 25 years, would estimate remaining stockpiles of 60 – 2,402 million litres of concentrate. Industry moved away from C_8 based perfluoro technologies over concerns for health and environment, with preference towards shorter chain C_6 perfluorinated compounds produced through telomerisation. The Swedish Chemicals Agency (2015) comments that while C_6 fluorotelomers are not manufactured using PFOA, it can be created as a by-product of the process. At the concluding step around 20% C_8 can be present in C_6 mixtures (including PFOA), which then undergoes a clean-up process to reduce C_8 species down to trace residues. However, studies exist suggesting that the concentration of	Only limited information on potential stockpiles exists which does not cover all geographies. However, based on the data identified the potential stockpiles in use could be significant (10s of millions of US gallons of concentrate, equivalent to hundreds of tonnes of PFOA and PFOA-related compounds). Equally costs associated with destruction and replacement could be significant, but are likely to be lower than remediation costs for contaminated sites following environmental release of PFOA. The size of in-use stockpiles of PFOA-based fire-fighting foams may be significant, suggesting an immediate ban could have socio-economic impacts. However, direct release of PFOA and/or PFOA-related compounds into the environment has significant implications. Additionally, PFOA and PFOA-related compounds can be present as by-products in shorter chain (C_6) telomer products. Concerns have also been raised about the environmental impacts of such shorter chain perfluorinated compounds. Therefore, the Committee

Use	Requested information	Estimated tonnages for PFOA and PFOA-related compounds per use globally	Summary of key points	Conclusion
			C_8 within C_9 products can be much higher than a trace (Swedish Chemicals Agency, 2015; Seow, 2013). Seow (2013) further comments that remaining C_8 perfluoro compounds in C_9 products can also degrade to PFOA in the environment. ECHA (ECHA, 2015) estimates 50–100 tonnes of PFOA-related compounds (CAS No: 70969-47-0) were in use in 2014, calculated to be between 1.18 – 23.6 –million US gallons of concentrate (assuming 0.1 – 1% wt/wt active ingredient in concentrates). The FFFC (2018) provided details of best practice for class B fire-fighting foams including non-fluorinated and AFFF based products which included selective use, containment of runoff and appropriate destruction. The guidance did however note that runoff cannot be contained in all incidents due to variability The RME provided details of clean-up costs for contaminated ground water where PFOS based foams had been used. Similar costs can be expected for PFOA based fire-fighting foams. For one example, this amounted to between £3.7–£30 million pounds (Klein, 2013).	should discuss the viability of non-fluorinated fire-fighting foams to cover all necessary applications and consider a recommendation that covers both PFOA and PFOA-related compounds in new use and existing stockpiles.

References

ABRAISCA	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Australia	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Belarus	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Brazil	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Canada	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
CVMA	2018	Submission from Canadian Vehicle Manufacturer's Association of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
FFFC	2018	Submission from the Fire-Fighting Foam Coalition of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
FluoroCouncil	2018a	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
FluoroCouncil	2018b	Comment received on PFOA first draft.
HCWH	2018	Submission from Healthcare Without Harm of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
IPEN and ACAT	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
MedTech Europe	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Netherlands	2018a	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Netherlands	2018b	Comment received on PFOA second draft.
Sweden	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.
Switzerland	2018	Comment received on PFOA second draft.
UK	2018	Submission of information specified in Annex F to the Stockholm Convention pursuant to Article 8 of the Convention.

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ECHA	2014a	EU ANNEX XV Restriction report on a Proposal for a restriction of PFOA, it salts and PFOA-related compounds under the REACH regulation EC 1907/2006
ECHA	2014b	Registered substances. Available from: https://echa.europa.eu/ de/information-on-chemicals/registered-substances Cited in Wang et al., 2015
ECHA	2015a	RAC and SEAC opinion on Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances under the REACH regulation EC 1907/2006
ECHA	2015b	Background document to the RAC and SEAC opinion on Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances under the REACH regulation EC 1907/2006
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UNITED NATIONS

UNEP

SC

UNEP/POPS/POPRC.14/4

Distr.: General
9 May 2018

Original: English

Stockholm Convention on Persistent Organic Pollutants

Persistent Organic Pollutants Review Committee
Fourteenth meeting
Rome, 17–21 September 2018
Item 4 (c) of the provisional agenda*

Technical work: process for the evaluation of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride pursuant to paragraphs 5 and 6 of part III of Annex B to the Convention

Process for the evaluation of perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride pursuant to paragraphs 5 and 6 of part III of Annex B to the Stockholm Convention

Note by the Secretariat

I. Introduction

1. Paragraph 5 of part III of Annex B to the Stockholm Convention on Persistent Organic Pollutants provides that the Conference of the Parties to the Convention shall evaluate the continued need for perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (PFOSF) for the various acceptable purposes and specific exemptions listed in Annex B on the basis of available scientific, technical, environmental and economic information. In accordance with paragraph 6 of part III of Annex B, the evaluation shall take place no later than in 2015 and every four years thereafter, in conjunction with a regular meeting of the Conference of the Parties.

2. In paragraph 1 of decision SC-6/4, the Conference of the Parties adopted the process for the evaluation of PFOS, its salts and PFOSF set out in the annex to that decision. Subsequently, in paragraph 7 of decision SC-7/5, the Conference of the Parties amended the schedule for the evaluation process, as set out in the annex to that decision, and decided to undertake the evaluation of PFOS, its salts and PFOSF at its ninth meeting.

3. By its decision POPRC-13/4, the Persistent Organic Pollutants Review Committee at its thirteenth meeting established an intersessional working group to undertake the activities specified in the process set out in the annex to decision SC-6/4 and agreed to work in accordance with the terms of reference set out in the annex to document UNEP/POPS/POPRC.13/INF/9.

4. In line with the terms of reference, the intersessional working group prepared a draft report on the assessment of alternatives to PFOS, its salts and PFOSF as set out in document UNEP/POPS/POPRC.14/INF/8, and the Secretariat prepared a draft report on the evaluation of PFOS, its salts and PFOSF as set out in document UNEP/POPS/POPRC.14/INF/9.

5. Furthermore, in paragraphs 7 and 8 of decision POPRC-13/2, the Committee noted that there was evidence that sulfluramid degraded to pentadecafluorooctanoic acid (PFOA) and that sulfluramid

* UNEP/POPS/POPRC.14/1.

was included in the risk profile on PFOS, its salts and PFOSF (UNEP/POPS/POPRC.2/17/Add.5) while the relevant CAS number was not included in Annex B to the Convention, and decided to proceed with sulfluramid within the process for the evaluation of PFOS, its salts and PFOSF pursuant to paragraphs 5 and 6 of part III of Annex B to the Convention.

II. Proposed action

6. The Committee may wish:

(a) To complete the report on the assessment of alternatives to PFOS, its salts and PFOSF, including recommendations, on the basis of the draft report set out in document UNEP/POPS/POPRC.14/INF/8, for consideration by the Conference of the Parties;

(b) To review and provide comments on the draft report prepared by the Secretariat on the evaluation of PFOS, its salts and PFOSF set out in document UNEP/POPS/POPRC.14/INF/9;

(c) To address how to proceed with sulfluramid, considering that the chemical may meet the definition of a PFOA-related substance and at the same time is included in the risk profile on PFOS, its salts and PFOSF while the relevant CAS number is not included in Annex B to the Convention.

UNITED NATIONS

UNEP

SC

UNEP/POPS/POPRC.14/5

Distr.: General
9 May 2018

Original: English

Stockholm Convention on Persistent Organic Pollutants

Persistent Organic Pollutants Review Committee
Fourteenth meeting
Rome, 17–21 September 2018
Item 6 of the provisional agenda*

Workplan for the intersessional period between the fourteenth and fifteenth meetings of the Committee

Workplan for the intersessional period between the fourteenth and fifteenth meetings of the Committee

Note by the Secretariat

I. Introduction

1. In accordance with paragraph 28 of its terms of reference,[1] the Persistent Organic Pollutants Review Committee prepares for each of its meetings risk profiles and risk management evaluations as required by Article 8 of the Stockholm Convention on Persistent Organic Pollutants. To undertake this task, the Committee establishes an intersessional working group for each chemical and agrees on a workplan for completing the drafts.

2. To support the working groups in carrying out their activities, the Secretariat has developed a draft workplan for the preparation of the risk profiles and risk management evaluations during the intersessional period between the fourteenth and fifteenth meetings of the Committee (see annex). The schedule may require adjustment, depending on the dates decided upon for the fifteenth meeting of the Committee.

II. Proposed action

3. The Committee may wish to adopt, with any amendments, the draft workplan for the preparation of risk profiles and risk management evaluations during the intersessional period between its fourteenth and fifteenth meetings.

* UNEP/POPS/POPRC.14/1

[1] Decision SC-1/7, as amended by decisions SC-4/20 and SC-5/11.

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Annex

Draft workplan for the preparation of risk profiles and risk management evaluations during the intersessional period between the fourteenth and fifteenth meetings of the Committee

Scheduled date	*Interval between activities (weeks)*	*Activity (for each chemical under review)*
20 September 2018	–	The Committee establishes an intersessional working group
28 September 2018	1	The Secretariat requests Parties and observers to provide the information specified in Annex E for risk profiles and Annex F for risk management evaluations
26 November 2018	8	Parties and observers submit the information specified in Annex E for risk profiles and Annex F for risk management evaluations to the Secretariat
14 January 2019	7	The working group chair and the drafter complete the first draft
28 January 2019	2	The members of the working group submit comments on the first draft to the chair and the drafter
11 February 2019	2	The working group chair and the drafter finish their review of the comments from the working group and complete the second draft and a compilation of responses to those comments
18 February 2019	1	The Secretariat distributes the second draft to Parties and observers for comments
1 April 2019	6	Parties and observers submit their comments to the Secretariat
6 May 2019	5	The working group chair and the drafter review the comments from Parties and observers and complete the third draft and a compilation of responses to those comments
13 May 2019	1	The Secretariat sends the third draft to the working group
29 May 2019	2	The members of the working group submit their final comments on the third draft to the chair and the drafter
12 June 2019	2	The working group chair and the drafter review the final comments and complete the fourth (final) draft and a compilation of responses to those comments
17 June 2019	<1	The Secretariat sends the final draft to the Division of Conference Services, United Nations Office at Nairobi, for editing and translation
12 August 2019	8	The Division of Conference Services completes the editing and translation of the final draft
19 August 2019	1	The Secretariat distributes the final draft in the six official languages of the United Nations
30 September – 4 October 2019	6	Fifteenth meeting of the Committee